

Government Relations Programs



CPSIA Requirements



UNITED STATES OF AMERICA
CONSUMER PRODUCT
SAFETY COMMISSION

- Third party testing mandatory:
 - Lead in substrate
 - Lead in paint and surface coatings
 - Some phthalates
- Children's Product Certificate mandatory
- Tracking labels mandatory
- Makes previously voluntary standards mandatory

We are in the brand protection business



- Compliance with Federal and state regulations is **not optional**
- It can be a strategic advantage and **increase your value** to your customer

Consumer Product Safety

Two Deaths Reported with Ace Bayou Bean Bag Chairs; Recall Announced Due to Suffocation and Choking Hazards

Consumers should stop using this product unless otherwise instructed. It is illegal to resell or attempt to resell a recalled consumer product.

Recall date: AUGUST 22, 2014

Recall number: 14-261



BRITA Recalls Children's Water Bottles Due to Laceration Hazard

Consumers should stop using this product unless otherwise instructed. It is illegal to resell or attempt to resell a recalled consumer product.

Recall date: AUGUST 19, 2014

Recall number: 14-257

Product responsibility is everyone's job

- **Distributors** must protect their customer's brand as if it were their own and do their own due diligence
- **Suppliers** must ensure compliance with all regulations and oversee all factories
- **Everyone** is responsible for providing safe products that will not cause harm to the end user
 - Education and awareness are critical



Government Relations State Affairs



2014 National Conference of State Legislatures

Placing Safe Products on the Market

1. Identifying hazards
2. Assessing risks
3. Implement risk reduction measures
4. Reducing risks in production
5. Traceability
6. Communicating use and warning information to consumers
7. Monitoring the product in the marketplace
8. Identifying any safety risks and managing them

Embracing Corporate Responsibility

- **Distributors are in the brand protection business**
- Compliance with Federal and state regulations is **not optional**
- **Damage to brand value** and hefty fines associated with non-compliance
- It can be a **strategic advantage** and increase your value to your customers
- Every day more end-buyers begin to care
- **Corporate responsibility is a key market differentiator**

Why End Buyers Care

- Responsible promotional products professionals will ensure that the **investment** made in their client's brand will be both promoted and **protected**.
- When regulations exist, compliance is required by law.
 - As consumers become more aware of product safety, demand for compliant products will increase
- Product responsibility is just **smart business**.
 - Increasingly, the target **audience wants assurances** that products comply with environmental, social and product safety regulations and standards.

Corporate Responsibility Facts

- 88% feel a responsibility to purchase products they think are socially and environmentally responsible.
- 92% of respondents would buy a product with social and/or environmental benefit.
- 90% of respondents would stop buying a company's products or services due to irresponsible business practices.
- 91% of global consumers are likely to switch brands to one associated with a good cause.
- 85% of this year's respondents say it's okay if a company is not perfect, as long as it is honest about its efforts.
- *2013 CONE Communications/ECHO Global CSR Study*

Where to Start

- Know your sources
 - Know your suppliers
 - Talk to your suppliers about compliance
 - Know that all products you sell meet regulatory requirements
 - Ask the right questions
 - If the item is a children's product, demand proof of compliance



Social Responsibility Basics

- Social standards refer to labor standards or working conditions and cover such things as:
 - Abuse of labor
 - Child labor
 - Hours and wages
 - Workplace conditions
 - Discrimination



Environmental Responsibility Basics

- Environmental responsibility considers all applicable environmental laws and regulations.
 - Manage your environmental footprint to minimize the adverse impact on the environment.
 - Manage energy, water and waste systems for maximum efficiency and minimal adverse impact on the environment.



Environmental Responsibility Basics

- Eco-friendly claims must be clearly stated and can be substantiated or proven.
- An environmental marketing claim should specify whether it refers to the product, the packaging, a component of the product or packaging or a combination of these.
- Environmental claims should not exaggerate or overstate attributes or benefits.
- All environmental symbols or logos on products or marketing pieces have to be substantiated or proven.

Product Responsibility Basics

- Even if the item is a general use item, there may be regulations beyond CPSIA



Congressional response

- In 2008, Congress passed the Consumer Product Safety Improvement Act (CPSIA)



CPSIA focus



- Defines a child as 12 and younger
- Applies to:
 - Children’s products
 - Childcare articles
 - Children’s toys

Lead in substrate

Substrate is the material of which something is made, and to which surface coating (i.e. paint) may be applied

— 100 ppm lead as of August 14, 2011



Lead Paint Rule

Decorated or scrapable
surface coatings



- 16 CFR 1303 in effect since 1978 at 600 ppm
- As of August 14, 2009, sets limit at 90 ppm

Phthalates

- **Applies only to children's toys and child care products**
- For all such products, DEHP, DBP, BBP – limit of 0.1%
- For all such products or any part of the product that can be placed in a child's mouth: DINP, DIDP, DnOP – limit of 0.1% (interim prohibition)
- Applies to accessible materials only (before and after use and abuse testing)

Children's Product Certificate (CPC)

- Importer or Domestic manufacturer is responsible for testing and certification
- All testing must be reflected in Children's Product Certificate (CPC) or General Conformity Certificate (GCC)
- Must be produced and made available for every youth order
- Sample certificates on the CPSC website

Children's Product Certificate (CPC)

- Identification of the product covered by this Certificate
- Citation to each CPSC product safety regulation to which this product is being certified
- Identification of the US importer, if applicable, or domestic (US) manufacturer certifying compliance of the product
- Contact information for the individual maintaining records of test results
- Date and place where this product was manufactured
- Date and place where this product was tested for compliance with the regulation(s) cited above
- Identification of any third-party laboratory on whose testing the certificate depends

Tracking Labels

- Required for all children's products manufactured after August 14, 2009
- Enhance recall effectiveness
- Required information:
 - Manufacturer name
 - Month & year of manufacture
 - City & state of manufacture
 - Batch or internal order number
 - Distributor PO number

Tracking Labels

- Must be permanent
 - Hangtags and adhesive labels **not** acceptable
- Supplier should include tracking label information
- Depending on changes made to the supplier's product, distributor may need to include additional tracking label markings

Secondary Tracking Label

When a distributor sources from an apparel supplier, contracts with a third-party decorator to apply ink or thread to a garment, and sells the product, the garment has been altered and requires **a second tracking label** for the same purpose as the first...

- A secondary tracking label is still required for embroidered items even though most embroidery threads are exempt from testing.

Secondary Tracking Label

The distributor is viewed as the manufacturer in this instance and becomes responsible for ensuring the contract decorator applies the secondary tracking label.

- Note: The manufacturer is responsible for all required documentation and recordkeeping.

Secondary Tracking Label

Required Information:

- Distributor's (Decorator's) name
- Month & year decoration was applied
- City & state where decoration was applied
- Decorator's batch or internal order number
- Distributor's PO number

XYZ Promotional Products	PO#	Nov
Las Vegas, Nevada	123456	2013

Tracking Labels

- Example using the PPAI tracking label system:

ps.ppa.org/SAMPLE003

Promotional Products Association International



PPAI Product Safety - Tracking Labels gives the owner of a promotional product a way to identify and contact the product manufacturer/importer in the event of a recall.

Product Tracking Label Information

Promotional Products Association International (UPIC: PPAI)
Dallas
09/15/2009, Order123456
Paul Elfstrom 972-252-0404

Secondary Tracking Label Best Practices

Label Location:

- Bottom hemline
- Inside back neck
- Sewn in as a label behind the original care/tracking label



Secondary Tracking Label Best Practices



- Permanent Tracking Labels
 - Mandatory for all children's products
 - Can be incorporated into the decoration if done at different time or by a different vendor



[LOOKUP](#)[CREATE](#)[MANAGE \(13\)](#)[ADMIN](#)

Create

[Single Registration](#)[Upload Multiple](#)

Single Registration

* Create a Code

product identifier, alphanumeric (A-Z, 0-9) and dashes (example: abc-123)

* Location of Production

city, state, country, factory (example: Irving, TX-Factory 5)

* Date of Production

format MM/DD/YYYY (example: 04/04/2014)

* Identifying
Characteristics

batch, run number, sources (example: BL-123 Bounce Ball)

* Contact Information

phone, email, etc (example: ☎ 888-426-7724, productsafety@ppai.org)

By clicking submit you accept the [terms of use](#).

Tracking Labels

- Example using the PPAI tracking label system:
ps.ppa.org/SAMPLE003

Promotional Products Association International



PPAI Product Safety - Tracking Labels gives the owner of a promotional product a way to identify and contact the product manufacturer/importer in the event of a recall.

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Recordkeeping

Manufacturer must maintain the following records:

- Copy of Children's Product Certificate for each product
- Records of each third party certification test
 - Separate CPC's and test records required for each manufacturing site
- Records of appropriate periodic tests
 - Periodic test plan and periodic test results
 - Production testing plan, production test results, periodic test results
 - Testing results of tests conducted by ISO 17025 testing lab and periodic test results
- Descriptions of all material changes, and the Certification tests related to these changes
- Records of undue influence procedures, including training materials and training records/attestations

Recordkeeping

- Records must be maintained for 5 years, and made available to CPSC upon request
- Records may be maintained in languages other than English if they can be provided immediately to CPSC and translated accurately into English by the manufacturer within 24 hours of a request

Best Practices

Distributors, ask your buyer...

1. Who is the **intended audience**? Will this item be distributed to children?
2. How will the **products be distributed**?
3. What **kind of logo** do you intend to use?
4. Do you typically **keep items in stock** for future use or do you **distribute all items**?
5. Do the customer's preferred products have **child-like appeal or playful elements**? Or do those products have "diminishing appeal" to the 12 and under crowd?

Best Practices

Distributors, tell your supplier and decorator...

The intended audience:

1. If the item will be given to children
2. The distribution method
3. The product you want

When distributors become suppliers...

- A distributor who sources direct **is a manufacturer**
- A distributor who uses a contract decorator would also be considered **a manufacturer**



How do you determine if something is a children's product?

- Whether the product is commonly recognized by consumers as intended for use by a child of the ages specified
 - **Similar product** (similar color, size, weight, materials and quality) marketed in retail store and primarily for children 12 and younger?
 - Historically **marketed** to young children?
 - Theme/media **appeal** considered primarily for children under 12?
 - Sold on websites, catalogues primarily for children under 12
 - Play value? Appeal more to children under 12 than 13+

String backpacks

- String backpacks are “general use” unless...
 - Theme/logo is primarily for children 12 and under
 - Marketed and/or intended to be distributed primarily to children 12 and under
 - Child-sized



Official sports apparel

- Sports apparel are “general use” unless...
 - Marketed and/or intended to be distributed primarily to children 12 and under
 - Child-sized



Lunch and other bags

- Lunch and other bags are “general use” unless...
 - Theme/logo is primarily for children 12 and under
 - Marketed and/or intended to be distributed primarily to children 12 and under
 - Child-sized



Water bottles

- Water bottles are “general use” unless...
 - Logo is primarily for children 12 and under
 - Marketed and/or intended to be distributed primarily to children 12 and under



Sporting goods

- Sporting goods are a general use item unless...
 - A toy version of a sporting good
 - Marketed and/or intended to be distributed primarily to children 12 and under



Soccer Ball Size	Player Age*	Ball circumference
1/Mini/Skills	All ages	18" - 20"
2/Midi	All ages	20" - 22"
3	Under 8	23" - 24"
4	12-Aug	25" - 26"
5	12 and up	27" - 28"



Children's Apparel Defined

- Infant and youth size garments



Federal Regulations for Children's Apparel

Drawstrings in children's apparel

- Hood and neck drawstrings on children's upper outerwear present a substantial strangulation hazard (sizes 2T to 12 or equivalent)



Federal Regulations for Children's Apparel

Drawstrings In Children's Apparel

- Waist and bottom drawstrings on children's upper outerwear also present a substantial product hazard.
 - Length of drawstrings at the waist and bottom of children's upper outerwear limited to 3 inches outside of the drawstring channel when garment fully expanded (sizes 2T to 16 or the equivalent)
 - Must be free of toggles, knots, and other attachments at the free ends of drawstrings.
 - If one continuous string, it must be bar tacked (stitched through)



L.E.A.D. Local Ohio



PPAI Director of Public Affairs Anne Lardner-Stone, Eric Ekstrand, MAS+, PPAI GR Manager Seth Barnett, Mitch Rhodus, CAS, and Jeff Shaw at the Ohio State House

Federal Regulations for Children's Apparel

CPSIA, Section 101 – Lead in substrate

- Applicable if the ink becomes part of the garment
- 100 ppm limit
- Composite and component testing allowed



Federal Regulations for Children's Apparel

CPSIA, Section 101 - Lead Paint Rule

- Applicable if the ink can be scraped off the garment
- 90 ppm limit
- Composite and component testing allowed
- HDXRF or wet chemistry

What About Bling?

Any hard attachments?

- Both lead limits apply to the decoration
- Use and abuse testing for attachments is recommended (small parts, sharp points, sharp edges)



Child-Care Articles Defined

Garment a child three years of age and younger would use for sleeping, feeding, sucking or teething

- Bibs
- Blanket
- Sleepwear



Federal Regulations for Child Care Articles

- CPSIA, Section 101 – Lead in substrate
- CPSIA, Section 101 - Lead in paint or ink
- Any hard attachments? Use and abuse testing for attachments is recommended (small parts, sharp points, sharp edges)
- CPSIA, Section 108 – Products Containing Certain **Phthalates**

Federal Regulations for Child Care Articles

CPSIA, Section 108 – Products Containing Certain Phthalates

- Applies to toys and child care articles only
- For any toy or child care article, DEHP, DBP, BBP are not allowed in concentrations exceeding 0.1%
- For any part of a toy or child care article, DINP, DIDP, DnOP are not allowed in concentrations exceeding 0.1% (interim prohibition)
- Interim banned phthalates limits apply to toys and child care articles that can be placed in a child's mouth whereas the permanent ban applies to any toy or child care article
- Inaccessible component parts are exempt

Materials Containing Phthalates

Phthalates may be found in the following materials:

- Soft or flexible plastics, except polyolefins
- Soft or flexible rubber, except silicone rubber and natural latex
- Foam rubber or foam plastic
- Surface coatings, non-slip coatings, finishes, decals, printed designs
- Elastic materials on apparel, such as sleepwear
- Adhesives and sealants

Assuring Ink Compliance

- Have all your inks tested
- Rely on ink suppliers' tests and component testing rule
- Perform third-party tests on finished product



What worries me?



- A **juvenile imprint** can transform a “general use item” into a “children’s product”
- Discovering the **intended audience** can be difficult
- Far too often, **test reports are out of date**, based on wrong standards, incomplete or for a different product
- Distribution site often unknown to the manufacturer

Testing and Labeling Pertaining to Product Certification – 16 CFR 1107

- Establish protocols and standards for ensuring continued testing of children's products
- Material change requirements
- **Safeguards against exercise of undue influence**
- Establish program for labeling of consumer products

Undue influence

- Undue influence occurs when one party uses his/her position to influence the other party to gain some advantage
- Pressure is typically exerted through persuasion rather than coercion

Undue influence

- Undue influence may result in undermining the integrity of testing data that can result in defective products that may injure or kill consumers, bring liability to the company and cause loss of business.

What is undue influence training?

- Undue influence training is training to ensure that manufacturers and their employees do not exert undue influence on testing laboratories to alter test methods or test results that serve as the basis for certifying a product's compliance under federal law.



If you interact with a third-party testing lab, what must you do?

- Establish procedures to safeguard against the exercise of undue influence by the manufacturer on a third-party laboratory
 - Written policy
 - Training and retraining
 - CPSC notification of any attempt to hide or exert undue influence over test results
 - Staff assurances

Undue Influence Written policy

- This policy should not only satisfy the rule, but also accentuate to staff its importance to the company
- Make the written undue influence policy visible and available to customers and the public
- Consider including the policy in the company code of conduct
 - <http://www.ppai.org/inside-ppai/ppai-code-of-conduct/>

Undue Influence Training

- All employees who interact with testing labs must undergo training to ensure that no one engages in actions or makes statements that will be considered undue influence.
- If the undue influence policy changes, all employees must be retrained.

Best practices to avoid unduly influencing a third party lab

- Ensure you follow appropriate sample selection protocols
- Do not test “golden samples”
- Don’t threaten to change third party testing providers because of an unsatisfactory test report
- Avoid developing personal relationships with the lab that could somehow influence test results

Obligation to exercise due care

- Applies to each domestic manufacturer or importer of a children's product.
- The importer is not required to train employees of foreign manufacturers, but must be sure to exercise due care.

Obligation to exercise due care

- Train your factories in your policy and advise them that their acts of undue influence on labs may cause you to rely on their supplied test reports for CPCs that can be deemed invalid by the CPSC and bring liability to you as the “certifier” for failing to exercise due care in preventing undue influence in your supply chain

Obligation to exercise due care

- If the importer receives a test report that is the result of undue influence, the CPSC could deem the certificate invalid and the CPSC may hold the domestic manufacturer/importer responsible for failing to exercise due care

Reporting Undue Influence

- If you witness or are aware of what you believe is an incident of undue influence, it is your responsibility to report it
- Ideally, you should report it to your immediate supervisor. If you are not comfortable doing so, you may report it to any company officer.
- The CPSC must be notified immediately of any attempt by the manufacturer to hide or exert undue influence over test results

Reporting Undue Influence

- For our purposes, any action or statement that undermines the credibility and validity of the testing process used for the certification of children's products is undue influence.
- If you have any doubt, report it.

Undue Influence Staff Assurances

- Manufacturers must inform their employees that allegations of undue influence may be reported confidentially to the CPSC, and manufacturers must tell their employees how to make such confidential reports.
- Reports alleging undue influence should be filed with the CPSC Office of the Secretary.

When undue influence occurs

- Employees who have engaged in undue influence should be disciplined in accordance with the company's policy for employee disciplinary actions
- Discipline may range from a written or verbal warning up and including termination of employment

Periodic testing

- Manufacturers must develop a Periodic Testing Plan to ensure continued compliance that includes:
 - Tests to be conducted
 - Intervals at which the tests will be conducted
 - Number of samples tested
- At minimum, periodic testing should be performed annually

Material Change Requirements

- A material change includes changes in:
 - Product design
 - Manufacturing process
 - Sourcing of component parts
 - Tooling
 - Changes in manufacturing facility
- New certification testing will be required on the “new product”

Recordkeeping

- Children's Product Certificate (CPC) for each product
- Records of each third party certification test
- Records of period tests
- Records of descriptions of all material changes
- Records of undue influence procedures—including training materials and training records of all employees
- These records must be kept for 5 years and may be maintained in languages other than English if they can be immediately provided to the CPSC and translated into English within 48 hours of a request by the CPSC

Consumer product labeling program

- MEETS CPSC SAFETY REQUIREMENTS
 - Label must be visible and legible
 - Product must comply with all applicable rules, bans, standards and regulations enforced by the CPSC
 - Additional labels may be added - Verbiage must not imply that the CPSC has tested, approved, or endorsed the product

Balloon Requirements

- Mechanical Hazards
- Toy Safety and Labeling
- Flammability
- Chemical Requirements
- General Labeling
- Packaging



Mechanical Hazards of Balloons

- Sharp Edges / Points
 - It is not likely to detect sharp edges or points on a balloon, but other components sold with the balloon may present a hazard
- Small Parts
 - Balloons are exempt from 16 CFR 1501
 - Any components sold with the balloons must comply
- Bite Test (Mouth Actuated Toys)
 - Mouth intended toys are tested at 100 pounds evenly applied for 5 seconds and maintained for an additional 10 seconds



Toy Safety – ASTM F963-11

- Use and Abuse Testing
 - Simulate the exposure of a toy to mechanical damage through dropping and other actions likely to be performed by a child during reasonable foreseeable use and abuse.
 - After testing the toy is examined for mechanical hazards



Toy Safety – ASTM F963-11

- Material Quality
 - Toys may be made from new or reprocessed materials and must be visibly clean and free from infestation.
- Safety Labeling
 - Packages containing latex balloons and toys or games containing latex balloons shall comply with the labeling requirements of 16 CFR 1500.19



WARNING:

CHOKING HAZARD--Children under 8 yrs. can choke or suffocate on uninflated or broken balloons. Adult supervision required.

Keep uninflated balloons from children.
Discard broken balloons at once.

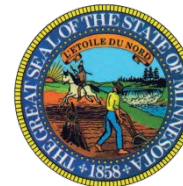
Flammability

- Product is considered a flammable solid if ignites and burns along its major axis with a self-sustaining flame at a rate greater than 0.1 inch per second.



Jewelry Product Safety

- CPSC (Consumer Product Safety Commission)
- ASTM (ASTM F963 & ASTM F2923)
- California Proposition 65 (Labelling Law)
- California Metal Containing Jewelry Law
- Additional U.S. State Laws
- FTC (Federal Trade Commission)
- Performance and Quality



CPSIA Requirements for Children's Jewelry

Factors to Consider:

Size and Shape

Materials Used

Colors

Cause & Effect

Sensory Elements

Level of Realism & Detail

Licensing & Theme

ASTM Requirements for Children's Jewelry

- **ASTM F2923-11**

- Specification for Consumer Product Safety for Children's Jewelry
- Defines children's jewelry as designed primarily or intended primarily for children 12 years of age and under (includes ornamentation)
- Mandatory in Rhode Island – Rhode Island Children's Jewelry Safety Act
- Requirements and test methods for specified elements and certain mechanical hazards in children's jewelry
- Includes recommendations for age labeling and warnings, guidelines for identifying the primary intended users of the jewelry and descriptions of numerous possible hazards posed by children's jewelry

ASTM Requirements for Adult Jewelry

- **ASTM F2999-13**
- Standard for Consumer Safety Specifications for Adult Jewelry
- Currently a voluntary standard
- Includes a migration threshold for acute exposure to cadmium as well as limits antimony, arsenic, barium, cadmium, chromium, mercury and selenium in surface coatings
- Requirements for lead, prescribes test methods, body-piercing jewelry, batteries, suction-tongue studs, magnets, batteries, and requires that statements of nickel content must be based on reliable testing

Jewelry and California Proposition 65

- Jewelry is frequently targeted
- Settlements can be used as a guideline for companies to determine what chemicals to test for and allowable limits
- If your company is named in a settlement, you must comply with the limits prescribed by the settlement
- Settlements include:
 - Phthalates $\leq 1,000$ ppm
 - Total Cadmium ≤ 75 ppm
 - Total Lead ≤ 200 ppm for substrates;
 - ≤ 90 ppm for coatings

California's Metal Containing Jewelry Law

- Born from Proposition 65 settlements with numerous jewelry manufacturers
- Limits Lead and Cadmium in certain jewelry
- Most distributors, suppliers and manufacturers cannot segregate products sold
- in California, so all products must comply with California regulations
- Using a warning label to comply with Proposition 65 does not relieve one
- of their obligations under the Jewelry Law



California Metal Containing Jewelry Law

- Regulations for jewelry are a matrix of:
 - Materials comprising jewelry
 - Jewelry components and their contact pattern with the user
 - Age of the user
- “Jewelry” means:
 - (1) Any of the following ornaments worn by a person: anklet; arm cuff; bracelet; brooch; chain; crown; cuff link; tie clip; hair accessory; earring; necklace; pin; ring; body piercing jewelry; jewelry placed in the mouth for display or ornament;
 - (2) any bead, chain, link, pendant or other component of an ornament specified in (1) above;
 - (3) a charm, bead, chain, link or pendant attached to shoes or clothes, that can be removed; or
 - (4) a watch in which a timepiece is a component of an ornament specified in (1) above, excluding the timepiece itself if the timepiece can be removed from the ornament.

Materials Required for Jewelry

Children's Jewelry

(Made for, marketed for use by, or marketed for children ages 6 and younger)



- Nonmetallic Class 1 Material
- Nonmetallic Class 2 Material
- A metallic material that is either a Class 1 Material or contains < 600 ppm Lead by weight
- Glass or crystal decorative components that weigh in total no more than 1 gram, excluding any glass or crystal decorative component that contains < 200 ppm Lead by weight and has no intentionally added Lead
- Printing ink or ceramic glaze that contains < 600 ppm Lead by weight
- Class 3 Material that contain < 200 ppm of Lead by weight

Materials Required for Jewelry

<p>Body Piercing Jewelry (Any part of jewelry that is manufactured or sold for placement in a new piercing or a mucous membrane)</p>	<ul style="list-style-type: none">• Surgical implant stainless steel• Surgical implant grade of titanium• Niobium (Nb)• Solid 14 karat or higher white or yellow nickel-free gold• Solid platinum• Dense low-porosity plastic, including by not limited to Tygon or Polytetrafluoroethylene (PTFE), if the plastic contains no intentionally added Lead
<p>All other Jewelry</p>	<ul style="list-style-type: none">• Class 1 Material• Class 2 Material• Class 3 Material

Jewelry Material Classes

Class 1 Materials:

- Stainless or surgical steel; karat gold; sterling silver; platinum, palladium, iridium, ruthenium, rhodium, or osmium;
- Natural or cultured pearls;
- Glass, ceramic, or crystal decorative components, including cat's eye, cubic zirconia, cubic zirconium (CZ), rhinestones, and cloisonné;
- Gemstones cut and polished for ornamental purposes (excluding aragonite, bayldonite, boleite, cerussite, crocoite, ekanite, linarite, mimetite, phosgenite, samarskite, vanadinite, and wulfenite);
- Elastic, fabric, ribbon, rope, or string (unless it contains intentionally added lead and is listed as a class 2 material);
- All natural decorative material, including amber, bone, coral, feathers, fur, horn, leather, shell, wood, that is in its natural state and is not treated in a way that adds lead; and
- Adhesive.

Class 2 Materials:

- Electroplated metal:
- Unplated metal not otherwise listed as a class 1 material;
- Plastic or rubber, including acrylic, polystyrene, plastic beads and stones, and polyvinyl chloride (PVC):
- A dye or surface coating

Class 3 Materials:

- Any portion of jewelry that meets both of the following criteria:
- Not a class 1 or class 2 material

Illinois Lead Poisoning Prevention Act Labeling Law

Children's Jewelry

If lead content in the surface coating or substrate is < 40 ppm no labeling is required

If lead content in the surface coating is > 40 ppm and ≤ 90 ppm labeling is required

If lead content in substrate is > 40 ppm but ≤ 300 ppm labeling is required

Adult Jewelry

If lead content in the surface coating or substrate is < 600 ppm labeling is required

“WARNING: CONTAINS LEAD. MAY BE HARMFUL IF EATEN OR CHEWED. MAY GENERATE DUST CONTAINING LEAD”

Battery Operated Jewelry

Mercury Content in Batteries

United States Public Law 104-142, 110 and State Legislation

Novelty items or items designed for children <5 mg per cell

Non-novelty items < 25 mg per cell

FCC Part 15

Applicable to devices that generate more than 1.705 MHz

FCC Declaration of Conformity or FCC ID on product

User manual with cautionary statements



Mercury Containing & Rechargeable Battery Management Act

Regulated batteries and rechargeable consumer products without easily removable batteries must be labeled in accordance with the regulation

Federal Trade Commission (FTC)

16 CFR Part 23

Guide for the Jewelry, Precious Metals and Pewters Industries

Retailers, vendors and manufacturers must truthfully represent and label the type, kind, grade, quality, quantity, metallic content, size, weight, cut, color, character, treatment, substance, durability, serviceability, origin, price, value, preparation, production, manufacture, and distribution of their merchandise.

Any disclosures should be clear and prominent

All labeled claims should be accurate

An illustration or depiction of a diamond or other gemstone that portrays it in greater than its actual size may mislead consumers, unless a disclosure is made about the item's true size.



Hypoallergenic and Nickel Free Claims

What does it mean, why is it important, and how do you properly describe and label your nickel free and hypoallergenic products?



Hypoallergenic Jewelry

Hypoallergenic jewelry is made out of pure metals such as platinum, karat gold higher than 18K, titanium, copper, stainless steel, and fine silver.

The term “Hypoallergenic” is not regulated by the FTC.

Only allowed to label “Hypoallergenic” if made entirely of one of the above listed metals.

Example:

A pair of earrings made out of a base metal or alloy with surgical steel posts. The earrings cannot be labeled “Hypoallergenic Earrings”. Label as “Earrings with Surgical Steel, Hypoallergenic Posts”.

Nickel Free Jewelry

If labeled “Nickel Free”, Nickel testing is required.

European Union, REACH Regulation

Migration of Nickel in post assemblies < 0.2
 $\mu\text{g}/\text{cm}^2/\text{week}$

Migration of Nickel in jewelry intended to come
in contact with prolonged skin contact < 0.5
 $\mu\text{g}/\text{cm}^2/\text{week}$

There are no federal regulations for nickel content in jewelry in the United States.

Misuse of Terminology

Descriptive terms and adjectives such as “Handmade, Handcrafted, Genuine, Authentic, Rare, Precious, Vintage, Antique, Made in the USA” are examples of terms often used in the jewelry industry when describing and labeling items. These terms are acceptable to use but only when they are in fact what they describe.

Examples:

“Handmade” means entirely handmade with no machine fabrication or cast metals. The use of hand powered tools is allowed.

“Made in the USA” means entirely made in the United States with no components being made or assembled outside of the United States.

Jewelry Quality and Performance Testing

Clasp

500 cycle test, force to open measured before and after testing

Yield point failure (destructive pull t

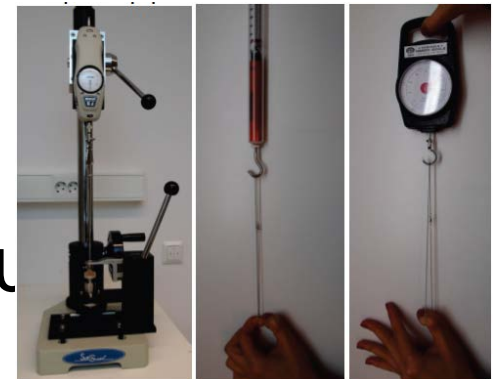


Post

Bending test (yield strength)

Tensile pull test

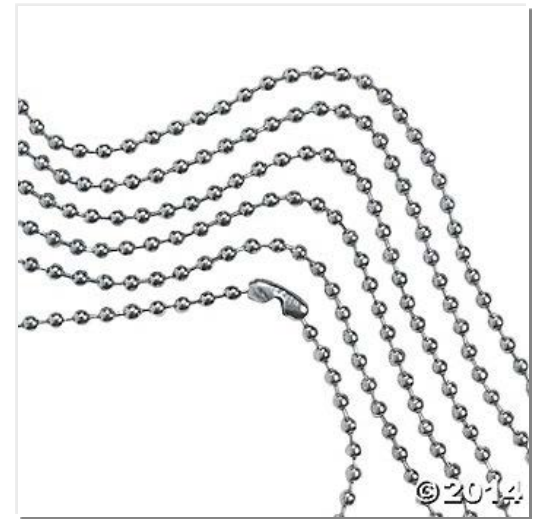
Cycle testing, force to open measured before and after testing



Quality and Performance Testing

Other quality and performance tests include:

- Chain strength
- Breakaway features
- Rockwell hardness testing
- Colorfastness
- Transit testing



Promotional Jewelry Considerations

Method of distribution

- Who will it be distributed to?
- How will it be distributed?
- Where will it be distributed?

Size

- Available in small sizes?

Logo / Theme

- Is it child appealing?

Federal and State Regulations

- Consider the various definitions of jewelry



Plush Toy Requirements

- Hazardous Conditions
- Mechanical Safety
- Chemical Requirements
- Flammability
- Performance
- Labeling



Hazardous Conditions

Sharp Accessible Points

- Not allowed before or after use and abuse testing

Sharp Accessible Edges

- Not allowed before or after use and abuse testing

Small Parts

- No toy intended for children of all ages can be small enough, without being compressed, to fit within the small parts cylinder
- ***Applicable before and after use and abuse testing***



Flammability

Flammability of Solids: Plush Stuffed Toys

- A product is considered to be a flammable solid if it ignites and burns along its major axis with a self-sustaining flame at a rate greater than 0.1 inches per second



Flammability

Flammability of Textile Fabrics

Plain Surface Fabrics

- Specimens are acceptable if they did not ignite, ignited but self extinguished or any combination thereof
- Average burn time is 3.5 seconds or greater

Raised Surface Fabrics

- Specimens are acceptable if they did not ignite, ignited but self extinguished or any combination thereof
- Average burn time is 4 seconds or greater

Plush Labeling

Country of Origin (19 CFR)

- Articles of foreign origin (or its container) imported into the United States must be marked with the name of the country of origin

CPSIA Tracking Label

- Product and its packaging must bear a permanent distinguishing mark as required to the extent practicable

Producer Markings (ASTM F963)

- Toys or their packaging must be legibly and conspicuously marked with the name and address of the producer or distributor

Plush Labeling

Age Grading: Plush Toys

- Toys should be labeled to indicate the minimum age for intended use or have such labeling on any packaging
- Stuffed plush toys are typically tested for the safety of all ages regardless of the age grading on the label because they are commonly recognized as appropriate for young children



Summary of State's Stuffed Toy Licensing and Labeling Laws

Uniform Label

- It is possible for manufacturers to utilize a uniform stuffed toy label which is good in all three states (Ohio, Pennsylvania and Massachusetts)
- There is no color, size, or type requirement for the Uniform Label, provided the print is legible and can be readily discerned
- The label must be affixed to the toy itself



Summary of State's Stuffed Toy Licensing and Labeling Laws

Uniform Label Requirements

- The Pennsylvania license number of the manufacturer or vendor. Ohio and Massachusetts will accept the use of a Pennsylvania toy registration number if that number is registered within these states and their fees are paid
- The name and principal place of business (city and state) of the manufacturer or vendor
- A statement that “All New Materials” (with type of material) or “All New (type) Material” was used in the manufacture of the stuffed toy

Pennsylvania Plush Regulations

License Fee

- \$25 initial registration
- \$25 annually

Labeling Requirements

- Manufacturers must submit detailed information as to the filler content of their stuffed toys and specimens of the toys selected at random to the Pennsylvania Licensing Authorities

Pennsylvania Plush Regulations

Registration Requirements for Foreign Manufacturers

- The manufacturer may register directly with the Department at the foreign manufacturer's locations. This is identical to the requirement for domestic manufacturers, or
- An importer may hold a stuffed toy registration on behalf of each foreign manufacturer represented. The Department does not permit "pooling" of registrations
- The Department is not requiring registration of each plant for domestic manufacturers but only to ensure that each foreign manufacturer is separately registered

Pennsylvania Classification of Flammability of Fabrics:

	No nap, pile, tufting, flock or other type raised fiber surface	Napped, pile, tufted, flocked or other type raised fiber surface
Class I (relatively slow burning)	When time of flame spread is 20 seconds or more for 12 square inches	When time of flame spread is over 7 seconds for 12 square inches
Class II (moderately flammable)	When time of flame spread is 8 to 19 seconds for 12 squares inches	Burns with a rapid surface flash in less than 7 seconds for 12 square inches, with no fusing or ignition of base fabric
Class III (relatively flammable)	When time of flame spread is 3 to 7 seconds for 12 square inches	When time of flame spread is 4 to 7 seconds, both inclusive for 12 square inches with fusing or ignition of base fabric
Class IV (rapid and intense burning)	When time of flame spread is less than 3 seconds for 12 square inches	When time of flame spread is less than 4 seconds for 12 square inches with fusing or ignition of base fabric

Pennsylvania Plush Regulations

Classification of Flammability of Non-Fabrics:

- Non-fabric materials include plastics, paints, and non-fabric portions of a stuffed toy. These materials which meet the requirements in Class V are accepted as having no unusual burning characteristics. Materials which have burning characteristics (Class VI) are considered dangerously flammable and recognized as unsuitable for stuffed toys because of their rapid burning and intense burning
- Class V – Materials are classified as normal flammability when a 9 square inch sample does not burn or flash the full area during a 4 second flame exposure
- Class VI – Materials are classified as rapid burning when a 9 square inch sample burns or flashes the full area during a 4 second flame exposure

Note: 16 CFR 1500.44 and 16 CFR 1610 standards may preempt the Pennsylvania flammability requirements if the Pennsylvania requirement is not identical to the federal regulation applicable to toys.

Massachusetts Plush Regulations

License Fee

- \$300 initial registration
- \$300 annual renewal

Labeling Requirements

- Same as Pennsylvania, Uniform Label is acceptable

Ohio Plush Regulations

Licensing Fee

- Annual fee of \$50
- File quarterly reports accompanied by a tax of four cents per item sold in the State of Ohio in the preceding quarter

Labeling Requirements

- Same as Pennsylvania, Uniform Label is acceptable

Battery Operated Plush Toys

- Labeling and instruction markings
- Mercury content
- Function and performance testing
- FCC requirements
- Noise level



Not Just Children's Products



- Federal regulations:
 - FDA (particularly drinkware, sunscreen)
- State regulations
 - Cadmium
 - Packaging
 - Lead
- International standards
- And more...

Applicable Laws, Regulations and Standards



Health Canada
www.hc-sc.gc.ca

Home | **Contact Us** | **Help** | **Search** | **Canada.ca**

Safety > Legislation & Guidelines > Acts & Regulations

Consumer Product Safety

Print | Text Size: S M L XL Help | Share


Canada Consumer Product Safety Act (CCPSA)



For Industry

- [Canada Consumer Product Safety Act - Webinar - October 5, 2011](#)
- [Watch a video on the new Act](#)
- **Mandatory Reporting**
 - [Guidance Document](#)
 - [Consumer Incident Report Form](#)
- [Frequently Asked Questions](#)

[More...](#)



Australian Competition & Consumer Commission

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Home > Business > Treating customers fairly > Product safety

Business

- Business rights & protections
- ▼ **Treating customers fairly**
 - Consumers' rights & obligations
 - Debt collection
 - Door-to-door & telemarketing sales
 - Lay-by agreements
- > **Product safety**
 - Repairs & spare parts
 - Unfair business practices
 - Warranties
 - Advertising & promoting your business

Product safety

All consumer products you supply must be safe and meet consumer guarantees under the Australian Consumer Law (ACL). You cannot sell banned products and you must ensure that your products or product-related services comply with relevant mandatory standards before they are offered for sale. There are also two mandatory notification requirements.

- ▼ [Selling safe products](#)
- ▼ [Product safety regulation](#)
- ▼ [Bans](#)
- ▼ [Mandatory standards](#)
- ▼ [Mandatory notification requirements](#)
- ▼ [Recalls](#)
- ▼ [Mandatory reporting](#)
- ▼ [Stay up-to-date](#)
- ▼ [More information](#)

Selling safe products

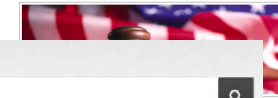


UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION

Home | **Recalls** | **Safety Education** | **Regulations, Laws & Standards** | **Research & Statistics** | **Business & Manufacturing**

Statutes | Voluntary Standards | Rulemaking | Federal Register Notices | Advisory Opinions | Regulations, Mandatory Standards and Bans

Regulations, Laws & Standards



Regulations, Mandatory Standards & Bans

CPSC publishes regulations to implement the laws it administers and enforces. These regulations specify the requirements that apply to individuals, businesses, and others.

[Search Regulations, Mandatory Standards, & Bans](#)

[Search the Code of Federal Regulations at GPOAccess.gov](#)

California Prop 65



- A state regulation that impacts the entire US supply chain
- Primarily a **warning** requirement
- Covers **900+ chemicals**
- Based on **exposure** levels
- Applies to general use as well as children's products

Cal Prop 65 The Basics No Pre-emption

- California's Office of Environmental Health Hazard Assessment (OEHHA) must annually publish a list of chemicals known to cause cancer, birth defects or other reproductive harm.
- List is approx. 900 chemicals now.
- Purpose is to give consumers a chance to make an "informed decision" to protect them from exposure to chemicals.



Cal Prop 65 Warning Label

- Provide a “Clear and Reasonable Warning” before knowingly and intentionally exposing anyone to a listed chemical

WARNING: This product contains a chemical known to the State of California to cause cancer.

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

Cal Prop 65 The Basics No Pre-emption



- Once a chemical is listed by OEHHA, companies have 12 months to comply with warning requirements under the regulation

Prop 65 is an “exposure” regulation



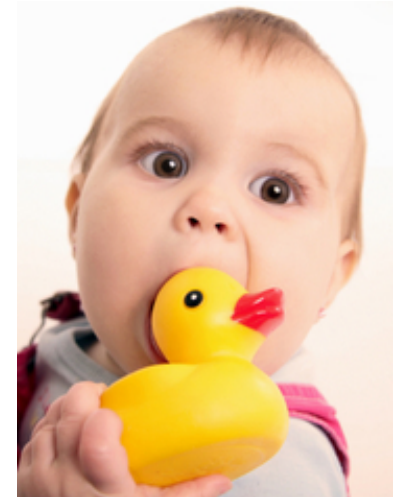
Methods of Exposure:

- Oral
- Inhalation
- Transdermal
- Hand-to-mouth



Measuring Exposure:

In most cases, exposure is measured in micrograms per day, based on average use of the product. Very difficult and expensive to defend a claim, since burden is on maker.



Recent Lead and Phthalate Cases:

Newer cases involving lead and phthalates have mirrored CPSIA content limits

Exemptions under Cal Prop 65



- If your company **has** **less than 10** **employees** (including part-time), it is exempt from warning requirements; recent amendment clarified this to apply to non-California companies too

Exemptions under Cal Prop 65

- Safe harbor levels have been established for many Prop 65 listed chemicals. Exempt if:
 - No Significant Risk Levels (NSRLs) for cancer-causing chemicals; and
 - Maximum Allowable Dose Levels (MADLs) for chemicals causing reproductive toxicity are not exceeded



Frequently Targeted Products

Under Prop 65

- Decorated glass and ceramic drinkware
- (lead and cadmium)



- Jewelry for adults and children
- (lead and cadmium)

- Padfolios, desk accessories, checkbook covers, luggage tags, phone covers
- (lead and phthalates)



- Leather goods, such as luggage, belts, wallets, footwear, eyeglass cases
- (lead)



- Tableware, Picnic products,
- Distilled spirits, Wine, Beer
- (lead, phthalates, sulfites)



- Plastic items, especially if made with PVC
- (phthalates)

- Sporting goods and children's toys
- (lead, phthalates)



- Electronic products
- (lead, cadmium, phthalates)
- Items with an electrical cord (phthalates)

California Proposition 65

Settlements

- Ceramicware that is externally decorated
- Aluminum cookware
- Beverage containers with colored artwork, made of glass, plastic, ceramic, resin, vacuum metalizing, dolomite, and/or metal
- Brass handled cookware
- Food use items such as glasses, pilsners, mugs, carafes, tumblers, bottles, condiment dispensers, bowls, cups, saucers, plates, trays, pitchers, punch bowls, serving utensils and serving platters
- Water bottles and soft beverage containers made of PVC

Enforcement of Prop 65



- State Attorney General's Office enforces Prop 65; District Attorneys and City Attorneys can too



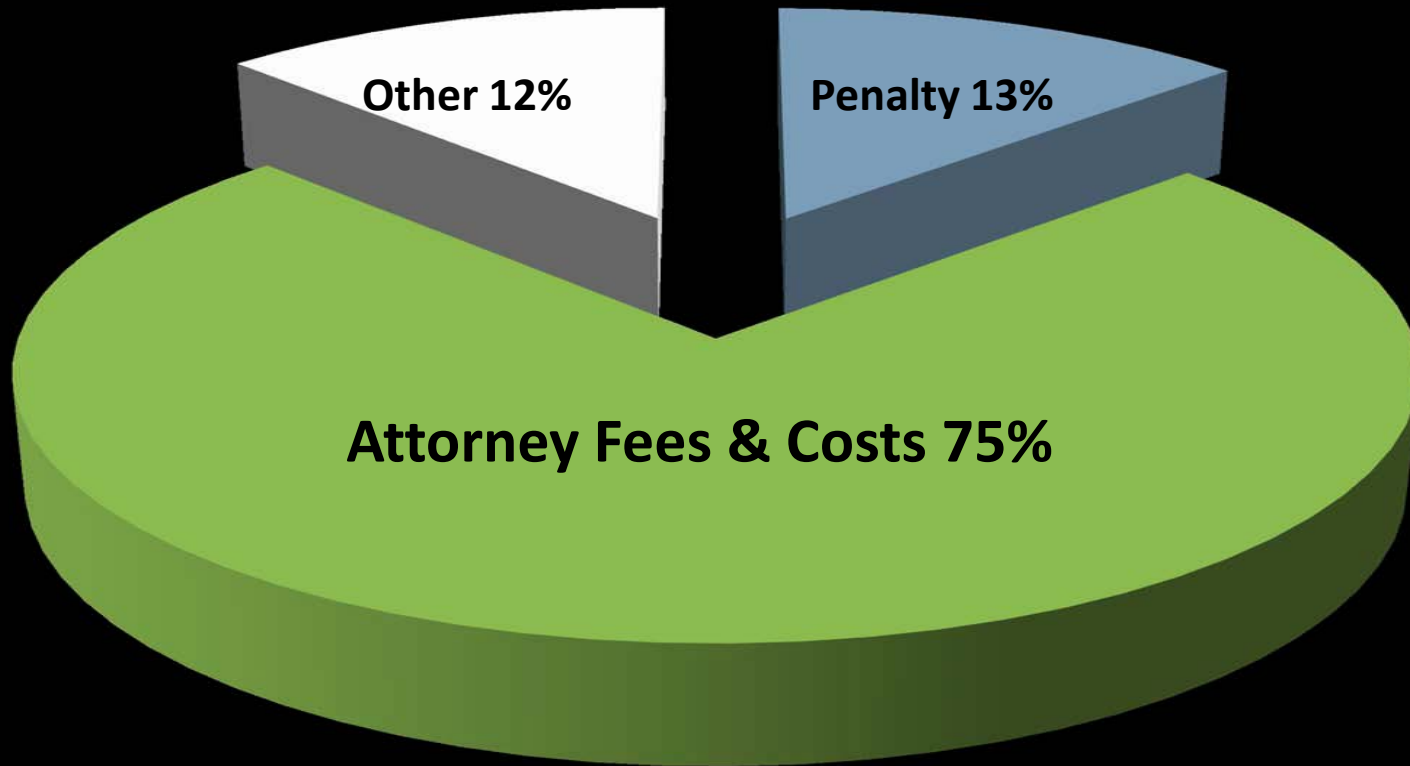
- Private Enforcers: any individual may bring an action to enforce.
- Very prolific; vast majority of claims

Enforcement of Prop 65

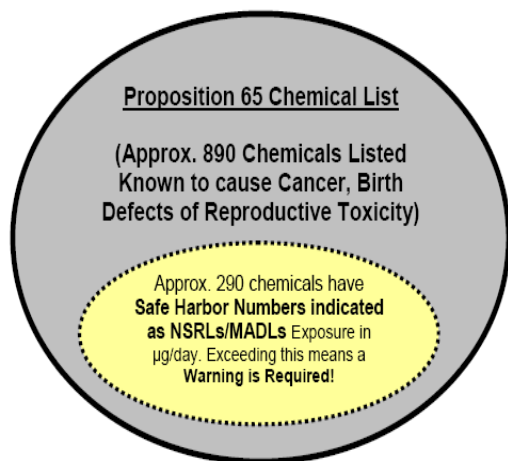


- Violations can be up to \$2,500/day per violation; private enforcers can enter into settlements and split \$\$ with State; the court approves and enters judgment against business owner.

Who Wins With Prop 65?



What Can We Do to Comply With Prop 65?



Check Chemical List

published and updated
by the **Office of
Environmental Health
and Hazard
Assessment** (OEHHA),
and can be found at
www.oehha.ca.gov

Confirm with Suppliers:

Confirm with supplier or
manufacture that none
of the chemicals have
been intentionally
added.

Test and Comply with Prop 65 Settlements:

- Ask your customer if the product may be distributed in CA;
- Ask for test reports;
- Have products tested for "usual suspects";
- Apply warning label.

Wait...there's more from California



On 8/28/13, the California Dept. of Toxic Substances Control approved the "[*Safer Consumer Product Regulation*](#)":

- Intent is to protect public health and/or environment;
- Took effect on 10/1/13;
- Establishes a process to [identify](#) consumer products and [chemicals of concern](#);
- Approx. 1200 chemicals in total may be identified; ~164 initial candidate chemicals

Green Chemistry



- 1) Designated 3 [priority products and chemicals](#) for assessment of safer alternatives
 - Children's foam padded sleeping products containing the flame retardant TDCPP, also known as chlorinated tris
 - Paint and varnish strippers and surface cleaners with methylene chloride
 - Spray polyurethane foam (SPF) systems containing unreacted diisocyanates (insulation)
- 2) Will require [alternative assessments](#) for Priority Products/Chemical combinations
- 3) Will impose [conditions for compliance](#) (i.e., warnings, notices, restrictions or bans on use of chemicals or products).

Green Chemistry: Promo

- Apparel, beauty, personal care and hygiene named as categories under the initiative's purview in a Safer Consumer Products (SCP) Draft Priority Work Plan.
 - Alongside apparel, a number of products in the promotional products industry such as body wash and soaps, lotions, and lip balms and gloss could be affected by these regulations.
- The work plan does not specifically identify priority products or chemicals of concern.
 - Lists categories from which those products may come.
 - The department says the plan gives manufacturers, importers and retailers a level of predictability regarding the types of products that can be considered for evaluation over the next 3 years.

WASHINGTON STATE CHILDREN'S SAFE PRODUCTS ACT



• “Chemicals of High Concern” to Children

- State is developing a list of chemicals that manufacturers must report on; 66 CHCC's have been listed to-date;
- CHCC's include: BPA, phthalates, formaldehyde, mercury, cadmium, etc.;
- Children's Product “Tiers” classification method, depending on “mouthable” or contact with skin or mouth aspects of the product;
- Manufacturers must report to WA State if their products contain any CHCC's if exceed an established concentration limit (if intentionally added) or 100ppm if classified as a trace “contaminant” that is incidental to manufacturing.

Illinois Lead Poisoning Prevention Act



- Products or packaging must have a warning label if:
 - Toys, child care articles (6 yrs. and under) and children's jewelry (12 yrs. and under) if lead in surface coatings is greater than **40ppm**;
 - Child care articles and children's jewelry if lead in substrate is >40 ppm
 - Products for adults if lead in surface coatings or substrate is greater than 600ppm.



Wisconsin

- Bisphenol-A (BPA) is banned in baby bottles and sippy cups (<3 yrs.);
- Children's items must be labeled "BPA-Free";

BPA:

- Suspected as an endocrine disruptor; risk to infants and young children;
- Also may be present in epoxy resin coatings in cans and aluminum water bottles;
- BPA also banned in 10 other states; mostly in baby bottles and sippy cups: CA, CT, DE, ME, MD, MA, MN, NY, WA, and VT; labeling not required;
- Legislation pending in other states.





Other States with Chemicals of Concern Regulations for Children's or All Products (enacted or pending):

- [Maine](#): Toxic Chemicals in Children's Products identifies 49 chemicals that are reproductive or developmental toxicants, endocrine disruptors or carcinogens
- [Connecticut](#), [Florida](#), [North Carolina](#), [Oregon](#), [New York](#)...

States with bans on certain kinds of flame retardants:

- TRIS, TDCPP, TDCP, TCEP, TCPP, PBDEs, decaBDE, and others;
- [Found mainly in children's clothing and furniture due to potential cancer risk through skin absorption or mouthing;](#)
- [Connecticut](#), [Delaware](#), [Illinois](#), [Massachusetts](#), [Maryland](#), [Maine](#), [Missouri](#), [North Carolina](#), [New Jersey](#), [New York](#), [Oregon](#), [Vermont](#), [Washington](#)...

Pennsylvania!



- Stuffed Toys
Registration; labeling
required
- PA is a NERC state

Ohio!



- Stuffed Toys
Registrations; fees;
OH will accept PA reg.
#
- Mercury in batteries
regulations

Mass!



- Stuffed Toys
Registrations;
labeling; fees; MA
will accept PA reg. #
- BPA regulations
- Polybag suffocation
warning regulation

Rhode Island Jewelry Legislation

- First state to adopt ASTM F2923-11 as mandatory
- Children's jewelry manufactured after December 18, 2012 must conform to the requirements of ASTM standard F2923-11, Specification for Consumer Product Safety for Children's Jewelry



Polybag suffocation warning



- Warning Label on Plastic Bags:
- If polybag is less than 1 mil thick;
- Opening is more than 5" wide at top;
- Should be trilingual; English, Spanish and French (for Canada);
- Required in CA, MA, NY, RI, VA

NERC Toxics in Packaging (Northeast Recycling Council)



Intent is to reduce the amount of 4 heavy metals in packaging materials: lead, mercury, cadmium and chromium-6.

Reducing the heavy metals will reduce the amount that leaches from landfills into underground water and streams.



Should test packaging materials for compliance or obtain documentation; currently 19 states are part of NERC alliance.

Restriction of Hazardous Substances

- California, Minnesota and New Jersey have adopted RoHS requirements for Electronic Devices
 - EN 1122 and EN 62321 method
- Under this law, a “covered electronic device” is defined as a video display device with a screen greater than four inches measured diagonally.



Drawstrings in children's clothing

- CPSC Final Rule on Drawstrings became effective in 2011, but CPSC has considered drawstrings in children's outerwear to be a substantial product hazard for years. Several CPSC recalls per year.
- New York and Wisconsin have specific requirements, banning hood and neck drawstrings on all children's clothing, but with limited exceptions for waist of upper and lower clothing drawstrings.



State Requirements

Hood and Neck Drawstring and Ties

	New York Law	Wisconsin Law	16 CFR 1120
Type of Apparel	All children's clothing	All children's clothing	Upper outerwear
Sizes	2T-12	0-16	2T-12
Requirements	No hood or neck drawstrings allowed	No hood or neck drawstrings allowed	Drawstrings and ties cannot be used in the head or neck area

State Requirements

Waist of Upper and Lower Clothing Drawstring

	New York Law	Wisconsin Law	16 CFR 1120
Type of Apparel	Children's upper and lower clothing	Children's upper outerwear	Children's upper outerwear
Sizes	2T-16	0-16	2T-16
Requirements	<ul style="list-style-type: none"> - No toggles, knots or other attachments - The drawstring must be attached to the garment's midpoint - 3 inch rule 	<ul style="list-style-type: none"> - No toggles, knots or other attachments - The drawstring must be sewn at the midpoint of the channel, so it cannot be pulled out of the channel - 3 inch rule 	<ul style="list-style-type: none"> - No toggles, knots or other attachments - The drawstring must be sewn at the midpoint of the channel, so it cannot be pulled out of the channel - 3 inch rule

What can I do for my company?

- Adopt Best Practices:
- Source from only trustworthy and knowledgeable vendors;
- Develop company requirements and standards for compliance;
- Educate your vendors of your requirements;
- Require written verification of compliance with state and federal regulations;
- Take other steps to make your company a “hard target”.



L.E.A.D. 2014

Meetings on the Hill



Jim Socci, Charles
Machion with Rep.
Michael Fitzpatrick
(PA)

Debra Simonette,
MAS, T. Neal Munn,
MAS with Rep. David
Price (NC)



General Requirements – Certification Testing

- Third party testing by CPSC approved lab is mandatory on all children's products to support Certification
- Manufacturers must submit a sufficient number of samples for testing. Number of samples must be sufficient to provide a “high degree of assurance” that the tests accurately demonstrate the ability of the product to meet all applicable safety rules
- Corrective Action Plan: If sample fails Certification testing, manufacturer must investigate reasons for failure and take necessary steps to address the reasons for failure

Best Practices – Test Reports

- Ask for an actual copy of the test report
- Compare the test report to the certificate – they should match
- Test report is dated within one year
- Testing was done by an independent third party lab
 - Must be CPSC-approved if children's product
- Specific to your product – look at the product description and photo
- Make sure all of the product components have been tested
- Make sure all regulations are covered
- Look for the actual test result

Responsibility for Test Reports

- The importer for products manufactured overseas and the US manufacturer for products manufactured domestically
- Based on a test of each product or a reasonable testing program
- Must “accompany” the applicable product or shipment of products covered by the certificate
- Must “furnish” the certificate to your distributors or retailers
- Provide a copy of the certificate to the CPSC and to the Commissioner of Customs upon request

Best Practices - Certificates

- Ask for an actual copy of the test report to back up the certificate
- Compare the test report to the certificate – they should match
- Certificate is dated within one year
- Based on testing by an independent third party lab
 - Must be CPSC-approved if children's product
- Specific to your product – should be a specific product, not a generic product or product line
- Make sure all regulations are covered

Not Just Children's Products



- Federal regulations:
 - FDA (particularly drinkware, sunscreen)
- State regulations
 - Cadmium
 - Packaging
 - Lead
- International standards
- And more...

FDA Overview

- Science-based regulatory agency
- Organized by product area
- Employs many types of scientific professionals, lawyers, analysts etc.
- Oldest comprehensive consumer protection agency in the US federal government.
- Began regulating food contact substances in 1958



FDA Responsibilities



- Protect the public health by assuring that foods are safe, wholesome, sanitary and properly labeled; human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective
- Protect the public from electronic product radiation
- Assure cosmetics and dietary supplements are safe and properly labeled
- Regulate tobacco products
- Advance the public health by helping to speed product innovations
- Help the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health
- *FDA's responsibilities extend to the 50 United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, and other U.S. territories and possessions*

FDA Definitions

- **Food Contact Substance (FCS):** Any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food
 - **Food Contact Material (FCM):** Made with the FCS and (usually) other substances - often (but not necessarily) a mixture, such as an antioxidant in a polymer - the composition may be variable
 - **Food Contact Article:** The finished product (film, bottle, tray, or whatever is formed out of the FCM)

What does the FDA regulate?

- Foods
- Dietary Supplements
- Human Drugs
- Vaccines, Blood Products, and Other Biologics
- Medical Devices
- Electronic Products
- Cosmetics
- Veterinary Products

FDA Regulations for Food Contact Material

- Title 21 Code of Federal Regulations
- Prior sanction letter
- Meeting the criteria for GRAS status
- Threshold of Regulation exemption request
- Effective Food Contact Notification (FCN)
- *May ask manufacturer for a Letter of Guaranty certifying that a particular product is acceptable for the intended food-contact use*

Legislative Education and Action Day



FDA Generally Recognized as Safe (GRAS)

- Designation that a chemical or substance added to food is considered safe by experts, and so is exempted from the usual Federal Food, Drug, and Cosmetic Act (FFDCA) food additive tolerance requirements
- Example: Stainless Steel

FDA Prior Sanctioned

- A substance whose use in or on food is the subject of a letter issued by FDA or USDA offering no objection to a specific use
- Prior sanction exists only for a specific use of a substance in food delineating level(s), condition(s) and product(s)

Food Contact Substance Notification Program

- Streamlined the way the FDA conducted business
- Established a notification process for food-contact substances
 - Defined a food-contact substance as **"any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect in such food"**
-
- Intended to replace the petition process as the primary means for authorizing new uses of food additives that are food-contact substances

FDA Ceramic Drinkware & Tableware

- FDA Guidelines 545.400 & 545.450
 - Internal Exposure Only
- California Proposition 65
 - Internal Exposure
 - Total Immersion – Externally Decorated Articles
 - NIOSH Wipe – Externally Decorated Articles
 - Lip & Rim – Decoration within top 20 mm of rim
- Society of Glass and Ceramic Decorated Products
 - Lip & Rim - Decoration within top 20 mm of rim



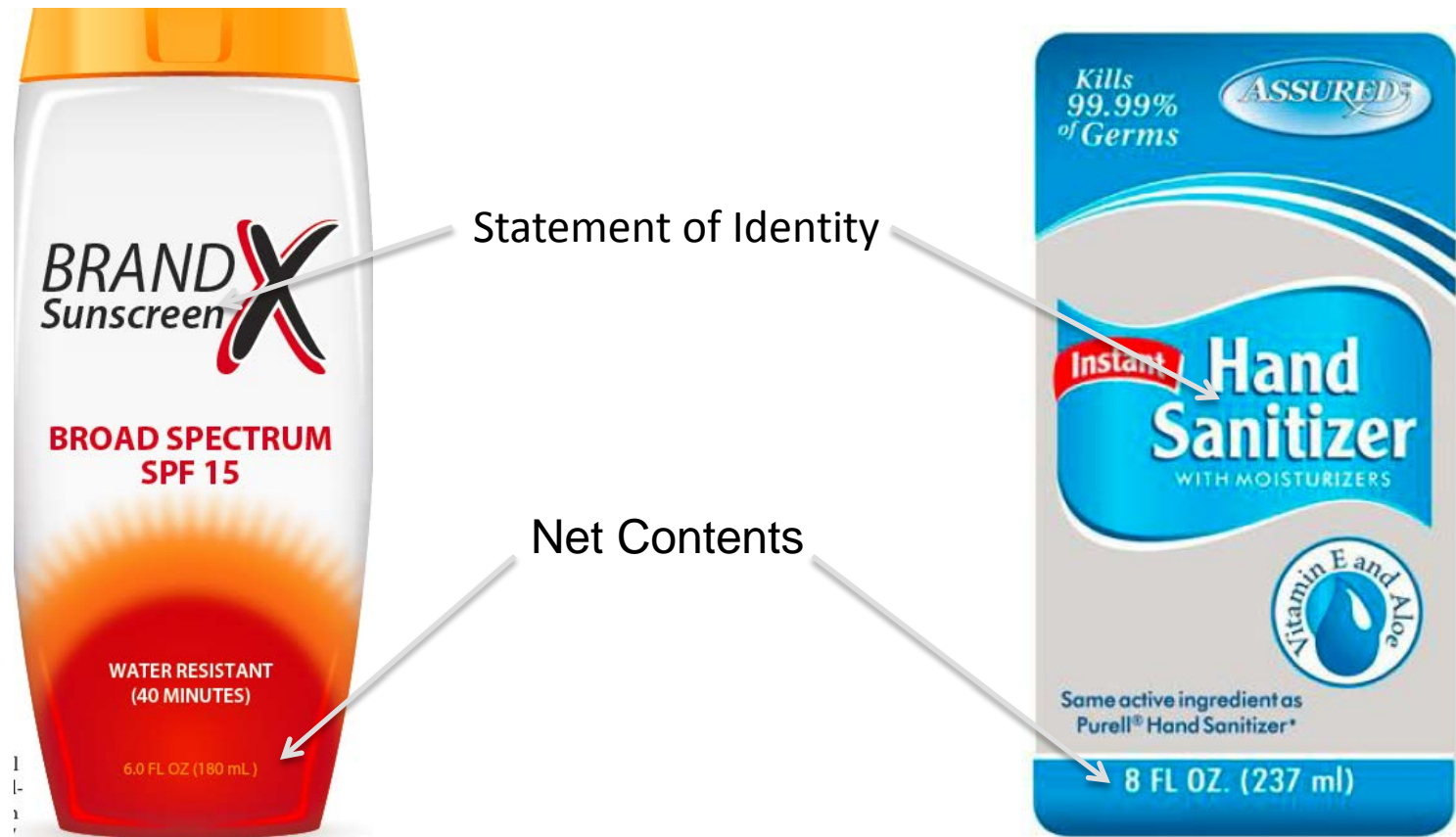
Quality Concerns and Performance Tests for Drinkware

- Leakage (burn hazard)
- Breakage
- Drinking spout detachment
- Handle temperature
- Handle strength
- Lid fit
- Microwave compatibility
- Dishwasher compatibility
- Heat retention
- Lid fit
- Leakage
- Stain resistance
- Breakage
- Handle strength
- Thermal shock

FDA Labeling Requirements

- The labeling requirements for promotional over the counter drug products is the same as those drug products for sale.
 - Focus on
- **Sunscreen Products and Hand Sanitizers**
 -
- Front – Principle Display Panel (**PDP**) 21 CFR 201.60
- Statement of Identity 21 CFR 201.61
- Declaration of Net Quantity 21 CFR 201.62

FDA Labeling Requirements - PDP



FDA Labeling Requirements - PDP

- Sunscreen Products – PDP
- You **cannot use** the following words to describe a sunscreen product:
 - Sunblock
 - Sweat proof
 - Waterproof
 - All day or extended wear
 - Instant protection
- The use of:
 - Water Resistant statements – May appear on the front panel provided the product passed required testing. Must have a specified time; (40 minutes) or (80 minutes)
- “Broad Spectrum” part of the Effectiveness claim may only be used for products that pass that specific testing. This provides protection against UVA and UVB ultraviolet rays.

FDA Labeling Requirements - PDP

SPF – Sun Protectant Factor is another part of the Effectiveness claim for the sunscreen and must have a prominent appearance and must follow the Broad Spectrum claim, when applicable. The following must be the same when both statements are used:

Font style, color and size

Color of background

The Water Resistant statement must appear just as it does on this label.



FDA Labeling Requirements

- Drug Facts Box 21 CFR 201.66, 201.300 through 210.327, 21 CFR 328 through 369 and current approved monographs (Sunscreen Products 21 CFR 201.327) - Black Type on Contrasting White Background
- ***Active Ingredients***
- ***Purpose***
- ***Uses***
- ***Warnings***
- ***Directions***
- ***Inactive Ingredients***
- ***Other Information***
- ***Questions***
- The font is italic and bold for each of these headings.

FDA Labeling Requirements - *Drug Facts*

<i>Drug Facts</i>	
<i>Active Ingredients</i>	<i>Purpose</i>
Avobenzone 3% Homosalate 10% Octyl methoxycinnamate 7.5%	Sunscreen

<i>Drug Facts</i>	
<i>Active ingredients.....</i>	<i>Purpose</i>
Ethyl Alcohol 62%	Antiseptic

- ***Drug Facts*** – The word is left justified, bold, italic and the first letter of each word is uppercase. The type size is the largest in the entire box.
- ***Active Ingredients*** – First letter of each word of the established active ingredient name is uppercase, each is listed in alphabetical order and the dosage amount follows the name. In both examples here, it is the proportion rather than the dosage amount.

FDA Labeling Requirements – *Drug Facts*

Active Ingredient – continued

Allowed Active Ingredients for Sunscreen Products

Aminobenzoic acid (PABA), 15%**

Avobenzene, 3% *

Cinoxate, 3%

Dioxybenzone, 3%

Ensulizole, 4%

Homosalate, 15%

Meradimate, 5%*

Octinoxate, 7.5%

Octisalate, 5%

Octocrylene, 10%

Oxybenzone, 6%

Padimate O, 6%*

Sulisobenzene, 10%

Titanium dioxide, 25*

Zinc Oxide, 24%*

**may not be combined with the ones marked with *. Each sunscreen active must contribute a minimum of SPF 2 to the product.

FDA Labeling Requirements – *Drug Facts*

- ***Active Ingredient*** – continued
- ***Purpose*** – Must be right justified, italic and bold. When the OTC drug monograph contains a statement of identity, it shall also be stated as the Purpose of the active ingredient. If no monograph exists, the principal pharmacological category or the principal intended action of the ingredient can be used.

FDA Labeling Requirements – *Drug Facts*

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see *Directions*) decreases the risk of skin cancer and early skin aging caused by the sun

Uses • hand sanitizer to help decrease bacteria on the skin. • when water, soap & towel are not available.
• recommended for repeated use

- **Use** or **Uses** – followed by the indications for the specific drug product.
- Sunscreens –
- **Uses**
- (bullet) helps prevent sunburn
- (bullet) The same as the second bullet item above when the SPF claim is 15 or higher. (**see Directions**) is in bold.

FDA Labeling Requirements – *Drug Facts*

- Bullet - 21 CFR 201.66(b)(4) and (d)(4)
- Means a geometric symbol that precedes each statement in a list of statements. Here limited to solid squares or solid circles. The same type of bullet must be used throughout the label.



FDA Labeling Requirements – *Drug Facts*

Warnings
For external use only
Do not use on damaged or broken skin
When using this product keep out of eyes. Rinse with water to remove.
Stop use and ask a doctor if rash occurs
Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Warnings	For external use only.
Flammable. Keep away from fire or flame.	
Do not apply around eyes. Do not use in ears & mouth	
When using this product, avoid contact with eyes. In case of contact flush eyes with water.	
Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.	
Keep out of reach of children. Children must be supervised in use of this product.	

Warning* or *Warnings

The above are examples of modified labeling formats.

To be clear, the following would be bold:

For external use only

Do not use

When using this product

Stop use and ask a doctor

Keep out of reach of children

FDA Labeling Requirements – *Drug Facts*

Warning or ***Warnings*** - continued

If not using a modified format each statement would be followed by a bullet.

If the product is broad spectrum but with a SPF of at least 2 but less than 15, the first statement under Warning is:

“Skin Cancer/Skin Aging Alert Spending time in the sun increases your risk of skin cancer and early skin aging. **This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.”**

FDA Labeling Requirements – *Drug Facts*

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
 - after 40 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. – 2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses
 - children under 6 months: Ask a doctor

Directions • pump as needed into your palms and thoroughly spread on both hands. • rub into skin until dry.

Directions

For sunscreens it may state “For sunscreen use”; “liberally” may be replaced with “generously”, an option may state “apply to all skin exposed to the sun”. If the product is not water resistant then:

- reapply at least every 2 hours use a water resistant sunscreen if swimming or sweating.

FDA Labeling Requirements – *Drug Facts*

Other information

- protect this product from excessive heat and direct sun

Other information • store at 20° C (68° to 77° F).

- may discolor fabrics.

Other Information – Information which is required by or is made optional under an appropriate OTC drug monograph, other OTC drug regulation or is included in the labeling of an approved drug application.

Sunscreens – The actual requirement is: protect the product in this container from excessive heat and direct sun

FDA Labeling Requirements – *Drug Facts*

Inactive ingredients

aloe extract, barium sulfate, benzyl alcohol, carbomer, dimethicone, disodium EDTA, jojoba oil, methylparaben, octadecene/MA copolymer, polyglyceryl-3 distearate, phenethyl alcohol, propylparaben, sorbitan isostearate, sorbitol, stearic acid, tocopherol (vitamin E), triethanolamine, water

Inactive ingredients water, triethanolamine, glycerin, propylene glycol, tocopheryl acetate, aloe barbadensis gel, carbomer, fragrance.

Inactive Ingredients – A listing of the established name of each inactive ingredient. The inactive ingredients are listed in alphabetical order.

The hand sanitizer list is not in compliance. Sometimes Other Information follows Inactive Ingredients rather than coming before it.

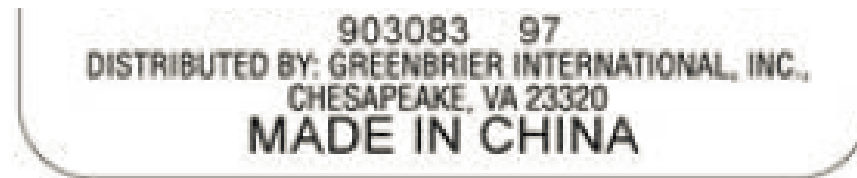
FDA Labeling Requirements – *Drug Facts*

- **Questions** – Must have the telephone number of a source to answer questions about the product. It is recommended that the days of the week and times of the day when a person is available to respond to questions also be included.
- The hand sanitizer does not have this and is not in compliance.

Questions or comments?
Call toll free 1-800-XXX-XXXX

FDA Labeling Requirements

- Country of Origin and Distributed by must be on the label. The hand sanitizer is in compliance but the sunscreen is not in compliance.



Labeling Concerns For Promotional Products Business

- Cosmetics
- Over-the-counter (OTC) drugs
- Consistency in Principle Display Panel (PDP) Requirements
 - Statement of Identity
 - Weight

Facility Registrations

- Do I have to register my facility with the FDA?
 - Only if you manufacture or store OTC drugs.
- Complicated process that requires specially registered computer with FDA, with security certificates held by the FDA through FDA's submission portal

Is it a Drug or a Cosmetic?

- Drug is defined as
 - Products intended to treat or prevent disease, or affect the structure or function of the body.
 - Examples
 - Sunscreen
 - Dandruff Shampoo
 - Acne treatment
 - Antiperspirants
 - Anything that makes a claim to treat or prevent

2014 Legislator of the Year

Rep. Renee Ellmers (NC)



With Chairman of the
Board Mark Jenkins,
MAS+ and Paul
Bellantone, CAE



Cosmetic

- Cosmetic is defined as: articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing beautifying, promoting attractiveness, or altering the appearance.”
- Doesn't claim to treat or prevent anything

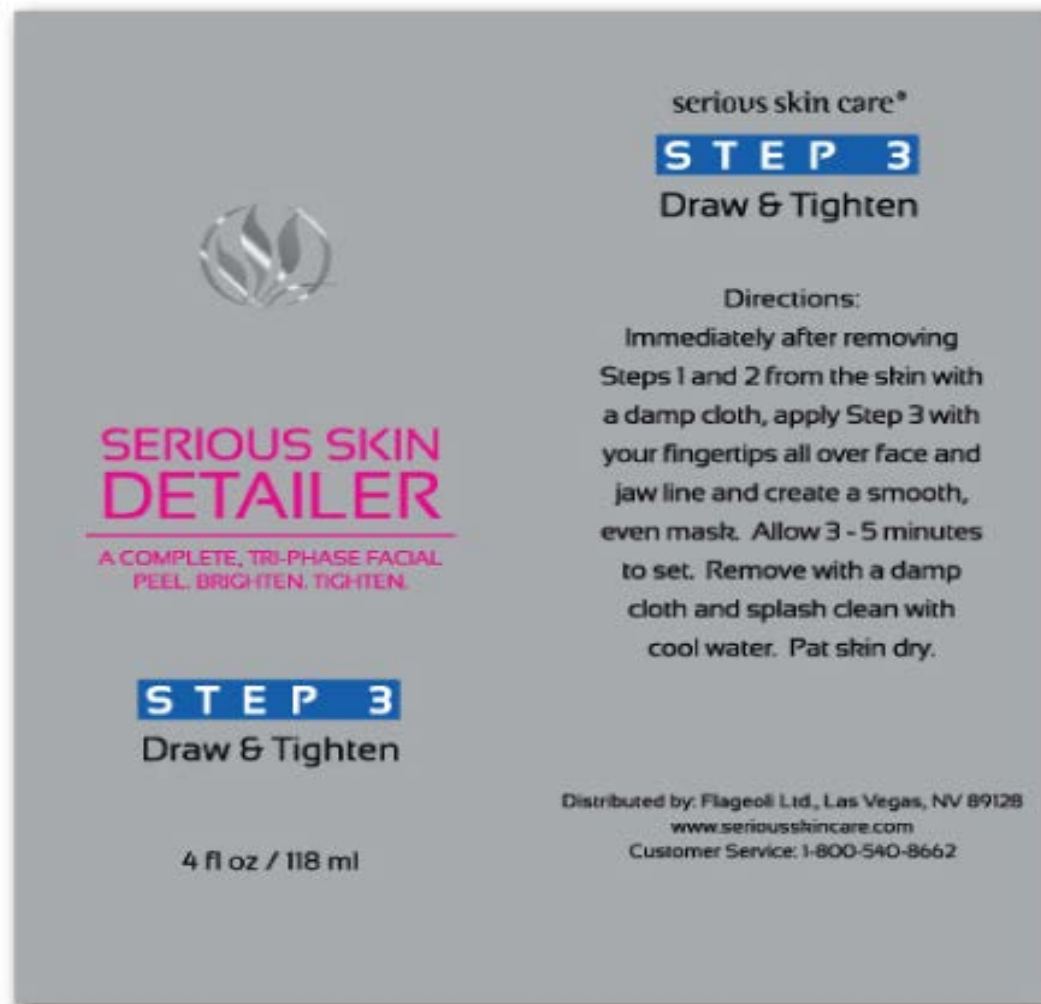
Cosmetic Continued

- Examples
 - Moisturizers
 - Perfumes
 - Lipstick
 - Fingernail polish
 - Cleansing shampoos
 - Hair colors

How Do I tell the Difference?

- Drugs make claims. Cosmetics do not.
 - “Balm” is a claim. Moisturizer is not.”
- Can it be both a drug and a cosmetic? Yes
 - A sunscreen that is also a moisturizer is both a cosmetic and an OTC drug if the moisturizing claim is on the container.
- Proper labeling is imperative for FDA compliance

Cosmetic Label Sample



OTC Drug Label Sample

Sunscreen Labeling According to 2011 Final Rule

If used as directed with other sun protection measures, this product reduces the risk of skin cancer and early skin aging, as well as helps prevent sunburn.

Only products labeled with both "Broad Spectrum" AND SPF15 or higher have been shown to provide all these benefits.



FDA

Drug Facts

Active Ingredients	Purpose
Avobenzone 3% Homosalate 10% Octyl methoxycinnamate 7.5%	Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
 - after 40 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. - 2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses
 - children under 6 months: Ask a doctor

Inactive ingredients

aloe extract, barium sulfate, benzyl alcohol, carbomer, dimethicone, disodium EDTA, jojoba oil, methylparaben, octadecene/MA copolymer, polyglyceryl-3 distearate, phenethyl alcohol, propylparaben, sorbitan isostearate, sorbitol, stearic acid, tocopherol (vitamin E), triethanolamine, water

Other information

- protect this product from excessive heat and direct sun

Questions or comments?

Call toll free 1-800-XXX-XXXX



CAUTION

- Regardless of the size of the container, it must be labeled properly. If you have a lip moisturizer, in a lip balm tube, making an SPF claim-it must be label as an OTC. So, you have to put all of the information on the sunscreen bottle on the label of that lip balm tube.

PPAI LAW Resources



@PPAILAW



www.ppailaw.org



PPAI L.E.A.D.



Useful Labeling Resources

Federal Register 21 CFR parts 201 and 310 Labeling and Effectiveness Testing; Sunscreen Drug Products for OTC Human Use – Final Rule:

<http://www.gpo.gov/fdsys/pkg/FR-2011-06-17/pdf/2011-14766.pdf>

Federal Register 21 CFR 201.66 Format and content requirements for OTC drug product labeling (Drug Facts Label):

<http://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol4/xml/CFR2012-title21-vol4-sec201-66.xml>

In September of 2011, the FDA presented a webinar titled “**Sunscreens Marketed Under the OTC Monograph System**”.

<http://www.fda.gov/downloads/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/UCM272114.pdf>

FDA Sheds Light on Sunscreens – Shows a sample Drugs Fact Panel for a Sunscreen

<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm258416.htm>

Tech Products – Lithium Battery Issues

- Ingestion incidents are life-threatening
- Packaging requires special precautions
- Overheating and fire dangers lead to scores of recalls
- Fire risks lead to regulations for air transport
- Defects in manufacturing reveal QA challenge
- Replacement is not always foolproof
- End-of-life disposal creates safety and handling challenges

UL LLC

- UL offers an extensive array of services to our diverse customers that support every stage of the product life cycle, from the testing of new technologies to market access.
- Product Safety
Environment Life &
Health Verification
Services Knowledge
Services
- Battery Websites:
- www.ul.com/batt &
www.ul.com/largebatt

Lithium Battery Safety Awareness Videos

- Civil Aviation Regulator (UKCAA) Video: Lithium Battery – Passenger Handling - Example Thermal Runaway
- http://www.youtube.com/watch?v=g_c6bRPdO_8
- Good Morning America - Samsung Cellphone - Non-OEM Battery Fire:
- <http://abcnews.go.com/GMA/video/cell-phone-catches-fire-24737967>
- UL Power Bank Video –
- <http://industries.ul.com/high-tech/batteries/power-bank-stay-in-charge-stay-charged/>




Hazards of Li-ion Battery


- **Hazards:**
 - Explosion.
 - Fire.
- **Cause - thermal runaway:**
 - Electrical abuse:
 - Over current.
 - Over voltage.
 - Over temperature.
 - Mechanical abuse
 - Other abuses:
 - Internal short circuit.
 - Transportation.
 - Miscellaneous.

Safety Testing Protocols and Standards for Lithium-Ion Battery Cells and Packs


Test Name	UN Manual of Tests and Criteria, Part III, Section 38.3	UL 1642	IEC 62133 2 nd Ed.	UN Manual of Tests and Criteria, Part III, Section 38.3	UL 2054	IEC 62133 2 nd Ed.
External Short Circuit	•	•	•	•	•	•
Abnormal Charge		•	•	•	•	•
Forced Discharge	•	•	•		•	
Crush	•	•	•			
Impact	•	•				
Mechanical Shock	•	•		•		
Vibration	•	•		•		
Heating		•	•			
Temperature Cycling	•	•		•		
Low Pressure (Altitude)	•	•		•		
Projectile		•				
Abusive Overcharge					•	
Limited Power					•	
Temperature					•	
250 N Steady Force					•	
Mold Stress Relief					•	•
Drop Impact					•	•
Continuous Charging			•			
Internal Short Circuit			(•)			




Mandatory




Depends on Application




Mandatory for Intl. Markets



Mandatory



Depends on Application



Mandatory for Intl. Markets

Although similar tests exist in the 3 standards, testing for UN, UL, and IEC standards do not have the same test methods, sample requirements, and/or defined sample condition.

What is UN 38.3?

- UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria.
- <http://www.unece.org/trans/danger/publi/manual/rev5/manrev5-amendments.html>
- Amendment 1 contains the full test program of 8 tests.
- Amendment 2 contains clarification on when to conduct the 6th test known as T6 (either Crush or Impact test)

UN 38.3 is Required by...

- US Department of Transportation (DOT).
- International Civil Aviation Organization (ICAO).
- International Air Transport Association (IATA).

Why UN 38.3 is Important?



Overview of UN 38.3 Transport Requirements

T1-T5 are conducted in sequence and on the bare battery cell as well as on a multi-cell battery pack. T6 and T8 are conducted on the bare battery cell. T7 is conducted on a single or multi-cell battery pack.

Test	Method Summary	Pass/fail
T1 Altitude Simulation	11.6 kPa for 6 h, ambient temp	nf, nl, nv, nd, nr, ocv \geq 90%
T2 Thermal	72 ± 2 °C to -40 ± 2 °C, hold temp for 6 h, 10 cycles, 24 h rest at ambient temp	nf, nl, nv, nd, nr, ocv \geq 90%
T3 Vibration	sinusoidal WF w log, 7 Hz→200Hz→7Hz in 15 min, 12 cycle for 3 h for 3 mutually \perp dir. 0.8 mm amp, Small Cell and Bat – 0.8 g peak acceleration;	nf, nl, nv, nd, nr, ocv \geq 90%
T4 Shock	half-sine, Small Cell and Bat: Peak acceleration 150 gn, pulse 6 msec;	nf, nl, nv, nd, nr, ocv \geq 90%
T5 External Short Circuit	55 ± 2 °C , $\leq 0.1\Omega$, 1 h or until case returns to 55°C temp, Check results for 6 h	nf, nr, nd, 170°C
Conditioning: Cells and small batteries: 1 st cycle and 50 cycles;		

Overview of UN 38.3 Transport Requirements

Test	Method Summary	Pass/fail
<p>T6 Impact / Crush</p> <p>Cell Conditioning: 1st cycle, 50% SOC</p>	<p>a) Impact test is for cylindrical with diameter greater than or equal to 18 mm; 9.1 kg mass dropped 61 cm onto 15.8 mm diameter bar across cell;</p> <p>b) Crush test is for other than cylindrical or cylindrical with diameter less than 18 mm; 13 kN flat plate crush at 1.5 cm/s rate until:</p> <ul style="list-style-type: none"> - force reached, or - 100 mV OCV drop, or - 50% deformation. <p>Check results for 6 h</p>	nf, nd, 170°C
<p>T7 Overcharge</p> <p>Battery Conditioning: Small: 1st cycle and 50 cycle</p>	<p>CC at $2I_{Cmax}$, Bat ≤ 18 V: CV = $2 \times V_{Cmax}$ or 22 V; Bat > 18 V: CV = $1.2 \times V_{Cmax}$, Check results for 7 days</p>	nf, nd
<p>T8 Forced Discharge</p> <p>Cell Conditioning: 1st cycle and 50 cycles</p>	<p>connect resistive load in series with test cell, cell forced discharged for time equal to rated capacity \div initial test current. Check results for 7 days</p>	nf, nd

Overview of UN 38.3 Transport Requirements

What is shipped?	Required Tests
Cells (single cell batteries considered a cell)	T1, T2, T3, T4, T5, T6 and T8
Multi-Cell Battery Packs	T1, T2, T3, T4, T5, T7
Battery Assembly ≤ 6200 Wh (w tested batteries & if <u>not</u> provided with a monitoring system to prevent oc, od, sc, and oh)	T3, T4, T5 and T7
Component Cell (only shipped as a component in a battery)	T6, T8
Single Cell Battery Packs	T7 (in addition to cell tests)

Power Banks with cells not previously test will need the cell and battery pack tested. Depending on the power bank's configuration (i.e. 1 cell or multi-cell) it will need either the T7 test or T1-T5 in sequence + T7 tests.

Why talk about other safety standards?

Safety in Production



ISO 10377
Consumer product safety –
Guidelines for suppliers

Presented by:
Robert Pollock, UL
Chair US Technical Advisory Group for ISO 10377



1. Safety Culture
2. Verification of raw materials, components and subassemblies
3. Production Quality Monitoring
4. Finished Product Testing



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All Things Election



In This Issue

Volume 4, Issue 10
21 November 2014

- All Things Election
- The 114th and Us
- Important Dates



It's Important!

With the 2014 midterm election now in the history books, Congress is working diligently to ensure a smooth transition before the conclusion of the current session. The election resulted in the Republicans taking a majority in both the House and the Senate creating the first truly divided government between the legislative and executive branches since the 104th Congress under the Clinton administration. There is a chance that while Congress may be very productive over the next two years the President could use his veto power to stall bills approved by Congress. During the 104th Congress President Clinton implemented similar tactics, which caused the government to shut down once beginning in November of 1995 and again beginning in December of 1995. However, after that time period faith was swiftly restored in Congress and the next few years resulted in the best national economics in decades. Today those on the Hill hope that compromise can be found quickly.

I. The End

December 12 will mark the conclusion of the 113th Congress, one of the least productive in American history. The much anticipated lame-duck session that began on November 12 has so far been uneventful. Those in the House spent nearly a week preparing and passing a bill that would fund the Keystone XL Pipeline only to have it stall out in the Senate by one vote. Senators have been working to reorganize their leadership responsibilities for after they turn control over to the Republicans in January. Presently both houses are recessed until December 1 when they will have just shy of two



Why talk about other safety standards?

- While UN 38.3 is a mandatory regulation from the air transport and ground transport authorities, it focuses on the safety during transporting of the battery products, and not during actual operation of charging and discharging.
- Normally, an evaluation (done for certification purposes) to UL 2054 or IEC 62133 is a combination of construction analysis and product testing. The construction analysis includes:
 - Review of the product's design including:
 - Electrical Circuit
 - Product Ratings
 - Mechanical Properties
 - Verifying that sub-level components have required safety certification including:
 - lithium ion cell,
 - specific circuit components,
 - the plastic enclosure material

Briefing: UL 2054 & IEC 62133

Fundamental Difference

UL 2054 Scope

- **Reducing the risk** of fire or explosion when batteries used in a product.

IEC 62133 Scope

- **Safe operation** of batteries under intended use and reasonably foreseeable misuse.

→ UL 2054:

- Proactively simulate any possibility that may trigger hazards.
 - Through single fault
 - Open circuit or short circuit of a component that:
 - Is likely to occur in the circuit.
 - Would result in over charging / over discharging conditions.

Related Mobile Products and Recommended Testing/Certification

Type of Promotional Product	Type of Test Work or Certification Services	Deliverable
Portable Battery Power (aka Power Bank / USB Battery Back-Up Charger)	UL 2054 test report only (may include UL/CSA 60950-1 requirements)	<u>Not a certified product.</u> Test report stored with battery mfr. and/or supplier.
	UL 2054 certification for USA market	UL in a Circle Certification Mark (USA only)
	UL 2054+UL/CSA 60950-1 certification for USA/CAN market	UL in a Circle Certification Mark (USA/CAN)
	IEC 62133 CB for international market	CB Certificate (can be also test report only)
Wall Plug-In Charger and/or Adapter	UL/CSA 60950-1 or UL 1310 certification for USA market	UL in a Circle Certification Mark (USA only)
	UL/CSA 60950-1 or UL 1310+CAN/CSA-C22.2 No. 223 certification for USA/CAN market	UL in a Circle Certification Mark (USA/CAN)
Bluetooth Audio/Video Device	UL 60065 test report only	<u>Not a certified product.</u> Test report stored with mfr. and/or supplier.
	UL 60065 certification for USA market	UL in a Circle Certification Mark (USA only)
	UL 60065 + CAN/CSA-C22.2 No. 60065 certification for USA/CAN market	UL in a Circle Certification Mark (USA/CAN)
	IEC 60065 CB for international market	CB Certificate
	Bluetooth Frequency Testing – FCC Part 15.247 (USA)	Test Report
	Bluetooth Frequency Testing - EN300-328 (Europe)	Test Report
	Bluetooth Frequency Testing - Other Bluetooth Standards	Test Report
Portable Vehicle Battery Adapter	UL/CSA 60950-1 or UL 2089 test report only	<u>Not a certified product.</u> Test report stored with mfr. and/or supplier.
	UL/CSA 60950-1 or UL 2089 for USA/CAN market	UL in a Circle Certification Mark (USA only)
	UL/CSA 60950-1 or UL 2089 + CSA-C22.2 No. 107.2 certification for USA/CAN market	UL in a Circle Certification Mark (USA/CAN)
Laser Pointers	IEC 60825-1 test report only	<u>Not a certified product.</u> Test report stored with mfr. and/or supplier.
	IEC 60825-1 CB for international market	CB Certificate (can be also test report only)
	FDA/CDRH Informative Laser Report	Confirms FDA/CDRH laser safety requirements
	IEC 60825-1 or FDA/CDRH testing only	Letter report - test results and laser classification

UL Listing

- The UL Listing Mark is one of the most common UL Marks. If a product carries this Mark, it means UL found that representative product samples met all UL's safety requirements.
- There are three variations of UL's Listing Mark: one used only in the United States, one used only in Canada and one for both the United States and Canada. The C-UL Mark is applied to products for the Canadian market. The products with this type of Mark have been evaluated to Canadian safety requirements, which may be somewhat different from U.S. safety requirements. The optional C-UL-US Mark indicates compliance with both Canadian and U.S. requirements.



UL Listing

- A UL Listing Marking appearing on a product typically consists of four required elements:
 - "UL in a circle" symbol
 - Word "Listed"
 - Product name or company name/file number
 - Issue/serial number or alphanumeric control number
- An example battery pack that would have UL Listing would be one with a fire and mechanical enclosure and also demonstrated ability to be a limited power source with limited hazardous voltage and current at the terminals.



UL Recognition

- The UL Recognition Mark is rarely seen by consumers because they are specifically used on component parts that are part of a larger product or system. These components may have restrictions on their performance or may be incomplete in construction. It also means UL found that representative product samples met **some but not all** UL's safety requirements.
- There are three variations of UL's Recognized Component Mark: one for the United States only, one for Canada only and one for both the United States and Canada. The C-UR Mark is applied to components only used in the Canadian market. Components with this type of Mark have been evaluated to Canadian standards. The optional C-UL-US Component Recognition Mark indicates compliance with both Canadian and U.S. requirements.



UL Recognition

- Components covered by UL's Recognized Component program are intended to be installed in another device, system or end product. They are to be installed at the factory, not in the field and they may have restricted performance capabilities that limit their use. When a complete product or system containing UL Recognized Components is evaluated, the end-product evaluation process can be streamlined.
- In addition, the battery pack UL 2054 evaluation would be allowed to waive certain tests such as Limited Power Source & Mechanical Enclosure Tests.
- An example battery pack that would have UL Recognized would be one with no enclosure (shrink wrapped) and does not demonstrate the ability to be a limited power source with non-limited hazardous voltage and current at the terminals.



UL Unlisted Component

- UL's Unlisted Component service is provided to end-product manufacturers, rather than component suppliers, for those situations where they have a customized component employed in a specific end-products that is not UL Certified.
- Under this program, the component is evaluated in accordance with the applicable component requirements, taking into consideration the specific end-product application. The component is only evaluated for factory installation, not field installation. Once the component is found to be in compliance with the applicable component requirements, the component is placed under UL's follow-up surveillance program. Since the component is intended for a specific application, no information is published on UL's Online Certifications Directory or UL's directories.

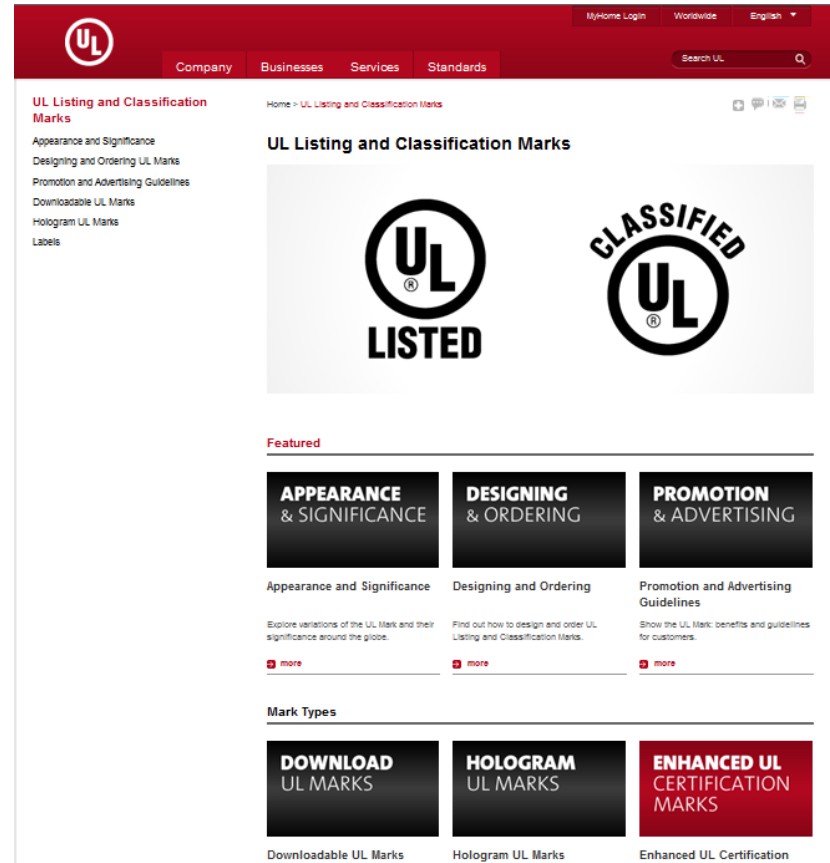
UL Unlisted Component

- Similar to UL's Component Recognition and Listing Service, the Unlisted Component Program creates value by increasing the confidence that the component complied with appropriate UL requirements when it was manufactured since it is under UL's Follow-up Program.
- Also similar to UL's Recognition service, the battery pack UL 2054 evaluation would be allowed to waive certain tests such as Limited Power Source & Mechanical Enclosure Tests.
- An example battery pack that would have UL Unlisted Component would be one where the end-product customer does not want any marking on their battery pack but only on the final end product, for example a Battery Operate Power Tool or a Battery Operated Handheld Device.

UL Website for more on UL Marks

- To know more about all the UL marks, including the ones used for Global Markets that are issued by UL, please visit:

<http://www.ul.com/global/eng/pages/corporate/aboutul/ulmarks/ul-listing-classification-marks/>



Wall Plug-In Chargers with USB outputs /
Vehicle Plug-In Charges with USB
outputs Safety –

Is yours certified?

Safety Awareness

- **Tiny, cheap, and dangerous: Inside a (fake) iPhone charger:**
- <http://www.righto.com/2012/03/inside-cheap-phone-charger-and-why-you.html>
- **iPad charger teardown: inside Apple's charger and a risky phony :**
- <http://www.righto.com/2014/05/a-look-inside-ipad-chargers-pricey.html>
- **Provides a detailed discussion of safety requirements for power supplies:**
- [Safety Considerations in Power Supply Design -
http://www.ti.com/lit/ml/slup227/slup227.pdf](http://www.ti.com/lit/ml/slup227/slup227.pdf)

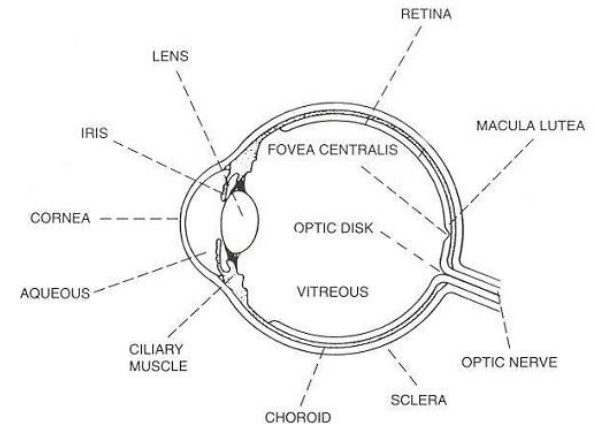
UL 60065: Safety - Requirements for Coin/Button Cell Batteries

- Background
- Developed by the Consumer Electronics Association (CEA) in response
- to field incidents involving injuries and fatalities of small children due to
- the ingestion of lithium coin/button cell batteries.
- The batteries can become lodged in the esophagus where, when in
- contact with tissue fluids, the batteries generate hydroxide through an
- electrolysis reaction. This hydroxide which forms causes alkaline burns
- and perforations of the esophagus.
- Serious injury may occur in
- as little as two hours.



Laser Pointer Safety Concerns - Background

- **Laser Pointers are generally used in a variety of applications, such as:**
 - Presentations
 - Alignment
 - Entertainment
 - General Misuse! (unfortunately)
- **Potential Safety Issues:**
 - Laser power is consistent along beam path even at great distances (miles or kilometers)
 - Temporary visual problems (“flash blindness”)
 - Possible eye injuries
 - Possible skin burns (larger laser pointers)
 - Easy to purchase
 - Large intended and unintended pool of users (children to business professionals)



Laser Pointer Safety Concerns - Background

- **US Laser Safety Requirements**

- Controlled by the CDRH – Center for Devices and Radiological Health
 - Branch of government under the US FDA
- Product Standard = 21 Code of Federal Regulations, Part 1010 and 1040
 - Required before a laser product can be sold, marketed, or imported into the US

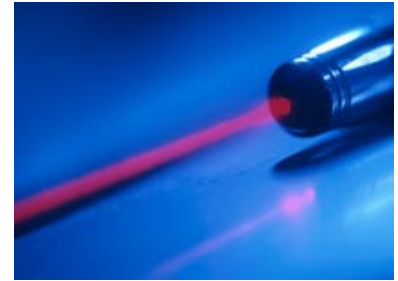
- **Outside-US Laser Safety Requirements**

- Product Standard = IEC 60825-1 – “Safety of laser products – Part 1: Equipment classification and requirements”
 - Required to show that a laser product meets the IEC based laser safety requirements

These Standards contain laser test methods, laser classification schemes, and requirements for laser labeling, laser construction features, and user manual content.

Laser Pointer Safety Concerns - Background

- US FDA sets limits for laser pointer emitted power (5mW – equivalent to Class 3R)
 - Other countries may have own power limits for these devices (example: 1mW – equivalent to Class 2)
- Laser Pointer manufacturers can self-certify compliance to the FDA laser requirements
- National Institute of Standards and Technology (NIST) research: many existing ‘self-certified’ laser pointers failed US FDA legal laser power limit
 - **90%** of green laser pointers failed*
 - **44%** of red laser pointers failed*
 - One laser pointer emitted 66.5mW (limit = 5mW)!!* - very dangerous
- Retailers / Distributors may have concerns about selling illegal / hazardous laser pointers
 - Online retailers and distributors could require a 3rd party such as UL to evaluate the laser pointer before they sell or distribute them



• *<http://www.nist.gov/pml/div686/pointer-032013.cfm>

L.E.A.D. Local Pennsylvania



Bruce Korn, CAS, George Jackson, Larry Whitney, PPAI GR Manager Seth Barnett, and Charles Machion at the Pennsylvania State Capitol

Methods for Evaluating Laser Pointer Safety

- Checking the safety of laser pointers could involve one or more of a variety of evaluation types based on the specific need – from laser power testing only, to full Certifications to the laser safety Standards



Methods for Evaluating Laser Pointer Safety

- **NEW in process: Full UL Certification (Listing) of a laser pointer**
- Full safety Certification that can result in the UL Mark upon successful completion
 - Includes: an evaluation of **ALL** potential hazards including electrical, flammability, laser radiation, etc.
- Benefit to Customer / Industry:
 - ✓ Can be used to help meet 3rd party laser safety check requirements retailers, distributors, etc. may require
 - ✓ Comprehensive Safety Certification of these devices by a 3rd party



Parties involved in the US and Internationally by mode of transportation

- Shipping “hazardous materials” by all modes in the US
 - US HMR
- Shipping “dangerous goods” by sea internationally
 - International Maritime Goods Code
- Shipping “dangerous goods” by air internationally
 - IATA Dangerous Goods Regulations (DGR) based on ICAO Technical Instructions

Information provided by Energy Assurance

Shipping Regulations

- **US Department of transportation (DoT)– Pipeline And Hazardous Materials Safety Administration (PHMSA)**
- Code of Federal Regulations (CFR) - Title 49 CFR parts - 100-185 – Hazardous Material Regulations (HMR)
- Governs all modes of transportation within the US (rail, aircraft, vessel and public highway)
- Applies “to each person who offers a hazardous material for transportation in commerce, causes a hazardous material to be transported in commerce, or transports a hazardous material in commerce”
- **Air transport is more internationally driven**
- Regulations developed by International Civil Aviators Organization (ICAO) and adopted into the International Air Transport Associations (IATA) Dangerous Goods Regulations (DGR).
- In most cases it is more stringent than US regulations. US regulations are noted as “State Variations” when they are more stringent.
- Air carriers and airport authorities will use IATA DGR.

Information provided by Energy Assurance

IATA/ICAO DG Regulations

- Identification of Dangerous Goods class is by the Proper Shipping Name and UN number within the identification table.
- 3 names under 2 numbers apply to Lithium ion cells and batteries
 - UN 3480 - Lithium ion batteries
 - UN 3481 – Lithium ion batteries contained in equipment and Lithium ion batteries packed with equipment
 - All 3 product types are classified as Class 9 (Miscellaneous) Dangerous Goods

Information provided by Energy Assurance

Definitions of Cell versus Battery

- Cells

- (UN) - A single encased electrochemical unit (one positive and one negative electrode) which exhibits a voltage differential across its two terminals.



- Battery

- (UN) Single cell battery means a single electrochemical unit fitted with devices necessary for use, for example, case, terminals, marking and protective devices AND
- Two or more cells which are electrically connected together and fitted with devices necessary for use, for example, case, terminals, marking and protective devices
- Units that have a primary function of providing power to another piece of equipment.



Information provided by Energy Assurance

Packing Instructions

- Provides specific details of the packaging methods as well as the general requirements that must be met to ship the named products.
 - PI 965 – Lithium ion or Lithium ion polymer cells and batteries
 - PI 966 – Lithium ion or Lithium ion polymer cells and batteries packed with equipment
 - PI 967 – Lithium ion or Lithium ion polymer cells and batteries contained in equipment

General Requirements

- Cells or batteries must be manufactured under a quality management system.
- No shipping of defective or damaged cells or batteries
- Protected from short circuiting
- Effective means to prevent accidental activation
- Placed in strong outer packaging
- Secured against movement within the outer packaging

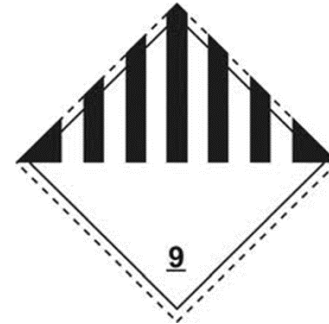


Information provided by Energy Assurance

PI 967-Section I

- Applies to
 - Batteries >100Wh or
 - Cells > 20Wh (~5.4Ah for a single 3.6V nominal) cell

PI 965 Section I only applies to larger cells and batteries contained in equipment – not typical for a power pack



Information provided by Energy Assurance

PI 967 Section II

- **Excepted from Class 9 Dangerous Goods Requirements**
 - Batteries <100Wh, cells <20Wh
 - Internal cell or battery must have passed UN Manual of Tests and Criteria Part III, subsection 38.3
 - Cells and batteries must be manufactured under a quality management system that meets the 9 points in section 3.9.2.6(e) of the regulations
 - For batteries, the Wh rating must be marked on the outside of the battery case
- **Other items that apply**
 - Passenger and crew baggage restrictions
 - Air mail restrictions
 - Reporting of accidents and incidents

Information provided by Energy Assurance

PI 967 Section II

Additional Requirements:

- Equipment must be packed in strong outer packaging
 - Suitable material or adequate strength
- Each package that contains more than 4 cells or 2 batteries contained in equipment must have
 - Label
 - Documentation

Information provided by Energy Assurance

PI-967 – Label and Documentation

Label:

- Lithium battery handling label



Documentation must include:

- Package contains Lithium batteries
- Handle with care
- Special procedures must be followed if damaged
- Contact number
- "Lithium ion batteries in compliance with Section II of PI967"
- Persons shipping the equipment must have adequate instruction
- Does NOT require a shipper's declaration of Dangerous Goods

Information provided by Energy Assurance



PI 967 Section II Over-pack boxes

- Individual **compliant** packages may be placed in an over-pack box, if
 - Each individual package is compliant with PI967, Section II on its own.
 - No packages within the over-pack contain a different substance that has its own DG regulations
 - Marked as “OVER-PACK”
 - Labeled with the Lithium Battery label



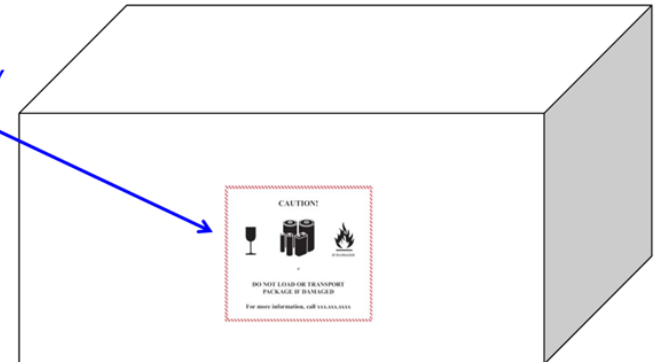
Information provided by Energy Assurance

Summary and example – Air shipments

Small Lithium ion cells and batteries contained in equipment transported by air per IATA

Classification	Excepted
Package Limits	5kg net weight per package
Packaging	Strong outer packaging
Marking	Lithium battery label (greater than 4 cells or 2 batteries)
Documents	Yes – PI967- Section II
Training of staff	N/A

Specific dimensions and red border apply only to air transport



Information provided by Energy Assurance

Battery Good/Bad News

- Bad News:
 - Internationally there are various regulations and interpretations related to the classification of power packs
 - These regulations are in constant flux and should be monitored as closely as possible.
- Good news:
 - Global harmonization is being pushed on all fronts
 - The industry is well represented through organizations like PRBA

Information provided by Energy Assurance

What is a Technical File?

- A comprehensive collection of information and documents that details everything about your product



Technical File Regulations

- Technical File requirements for the European New Toy Safety Directive (TSD)
- Record Keeping Requirements under the CPSC's "Reasonable Testing Program", 16 CFR 1107

Requirements for the European Technical File

- The EU TSD requires manufacturers to provide documentation demonstrating that toys comply with design manufacture and operational requirements
- The Technical File must be kept up to date and reflect any changes to the toy, legislation or standards
- The history of the product must be retained

Contents of the EU Technical File

- Detailed description of the design and manufacture
- List of components and materials used in toys
- Safety assessment(s)
- Conformity assessment procedure
- EC declaration of conformity
- Addresses of the places of manufacture
- Address of storage
- Test reports
- Internal production control procedure
- EC type-examination certificate (if applicable)

Required Content (1)

- **Detailed Description of the Design of the Toy**

- This information can be found within a product specification and is likely to include a description of the features, functions, age grade, performance requirements, packaging, instructions and a colour image of the toy.

- **Detailed Description of the Manufacture**

- This should identify the procedures and steps in the production process, e.g. melting, cutting.

Required Content (2)

- **List of Components and Materials Used**

- Typically contained within the Bill of Materials (BOM) and Bill of Substance (BOS) which identify all materials used in manufacturing the item
- The BOM lists raw materials, purchased parts and sub-assemblies
- The BOS contains more detailed information about each material used, such as the colorants and additives

- **Safety Data Sheets**

- For all chemicals, chemical preparations or mixtures used in the toy must be included.

Required Content (3)

•Safety Assessment

- Conducted to ensure that all hazards are identified (chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity) and adequately controlled by reference to the harmonised toy safety standards or other suitable means

•Conformity Assessment Procedure

- The procedure followed should be identified and described.

Required Content (4)

- **EC Declaration of Conformity**

- The format for this is defined within the directive. It must include a colour image of the toy and be completed and signed by the manufacturer.

- **Addresses of Manufacture and Storage**

- Addresses where the product has been manufactured and stored, including locations outside of the EU

Required Content (5)

•Test Reports

- To demonstrate that the product has been tested to the relevant harmonised standards
- A list of the harmonised standards that were applied should be held with the copies of the reports

•Conformity of Production

- Description of the means whereby the manufacturer ensured conformity of production with the harmonised standards, if the manufacturer followed the internal production control procedure referred to in Article 19(2)
- This can often be addressed by inclusion of quality assurance program details and quality assurance reports

Congressional District Visits



Members of Rep. Bob Gibbs (OH) staff with Chairman of the Board Mark Jenkins, MAS+, and PPAI GR Manager Seth Barnett

Required Content (6)

- If Toy has been Subjected to an EC-type Examination

- Notified body identification and copies of documents submitted
- EC-type examination certificate issued for the toy
- Description of the means whereby the manufacturer ensured conformity of the production with the product type as described in the EC-type examination certificate
- Copies of documents submitted to the notified body if the manufacturer submitted the toy to EC-type examination and followed the conformity to type procedure referred to in Article 19(3)

EC Declaration of Conformity

1. No ... unique identification of the toy
2. Name and address of the manufacturer or his authorised representative
3. This declaration of conformity is issued under the sole responsibility of the manufacturer
4. Object of the declaration (identification of toy allowing traceability). It shall include a colour image of sufficient clarity to enable the identification of the toy
5. The object of the declaration described in point 4 is in conformity with the relevant Community harmonisation legislation
6. References to the relevant harmonised standards used, or references to the specifications in relation to which conformity is declared
7. Where applicable: the notified body ... (name, number) ... performed ... (description of intervention) ... and issued the certificate:
8. Additional information:
 - **Signed for and on behalf of:**
 - **(place and date of issue), (name, function) (signature)**

On The Hill



Teki Hall and Todd Mawyer

Combined US Certificate/EC Declaration?

1. Unique identification of the toy that allows for traceability, with color image (US #1, EC #1 & #4)
2. Citation of each regulation, legislation, standards, specifications to which product is being certified as complying (US #2, EC #5 & #6)
3. Name and address of the manufacturer or his authorised representative within EC and US – this is individual/organisation maintaining records of technical documentation, DoC, etc (US #4, EC #2)
4. Identification of the US importer (may be manufacturer) or US domestic manufacturer (US #3)
5. This declaration of conformity is issued under the sole responsibility of the manufacturer (EC #3)
6. Date and place where this product was manufactured (US #5)
7. Date and place where this product was tested for compliance with the regulation(s) cited above (US #6)
8. Identification of any third-party laboratory on whose testing the certificate depends (US #7)
9. Where applicable: the notified body ... (name, number) ... performed ... (description of intervention) ... and issued the certificate (EC #7)
10. Additional information:
 - **Signed for and on behalf of:**
 - **(place and date of issue), (name, function) (signature)**
 - **(EC #8)**

CPSC's Reasonable Testing Program

- Required by Section 102 (b) of CPSIA
- Basis for GCC / CPC
- Proposed rule published May 20, 2010
 - Testing and Labeling Pertaining to Product Certification
- Public comment period through August 3, 2010
- Amendments published November 8, 2011
- Codified as 16 CFR Part 1107

Required Documentation - US

- **Production Testing Plan**
- **May include:**
 - Internal/external test reports of recurring testing
 - Process management records
 - Control charts
 - Statistical process control programs
 - Failure modes and effects analyses (FMEAs)
 - Factory QC plans
- **Material Changes**
- Records of any change in product's design, manufacturing process, or sourcing of component parts that may affect compliance
 - Certification tests on changed product or components as needed
- **Undue Influence**
- Written policy with training records

EU Recordkeeping Requirements

- The technical documentation has to be drawn up in one of the official languages of the European Community
- When market surveillance authority of a Member State requests the technical documentation it may pose a 30-day deadline for receipt, but this deadline can be reduced in the case of serious risk
- Manufacturers are obliged to keep the technical documentation for a period of 10 years after the toy has been placed on the market

Market Trends

- Organic food products have grown at a rate double that of conventional products
- A 2012 study of global executives by consultancy Accenture showed one-third of those surveyed could not keep up with demand for sustainable products and services.
- Brands such as Wal-Mart and Nike are phasing out hazardous chemicals and developing indexes to measure the environmental attributes of their products.
- Consumers are expecting more transparency.

Confusion about Environmental Claims

- Historical confusion about what is and what isn't green.
- Many 'vague' claims in our industry
- Use the newly revised Federal Trade Commission (FTC) Guidelines on the Use of Environmental Marketing Claims to understand 'rules' on:
 - Recyclability
 - Recycled content
 - Biodegradability
 - Eco-Friendly/Natural or other vague claims

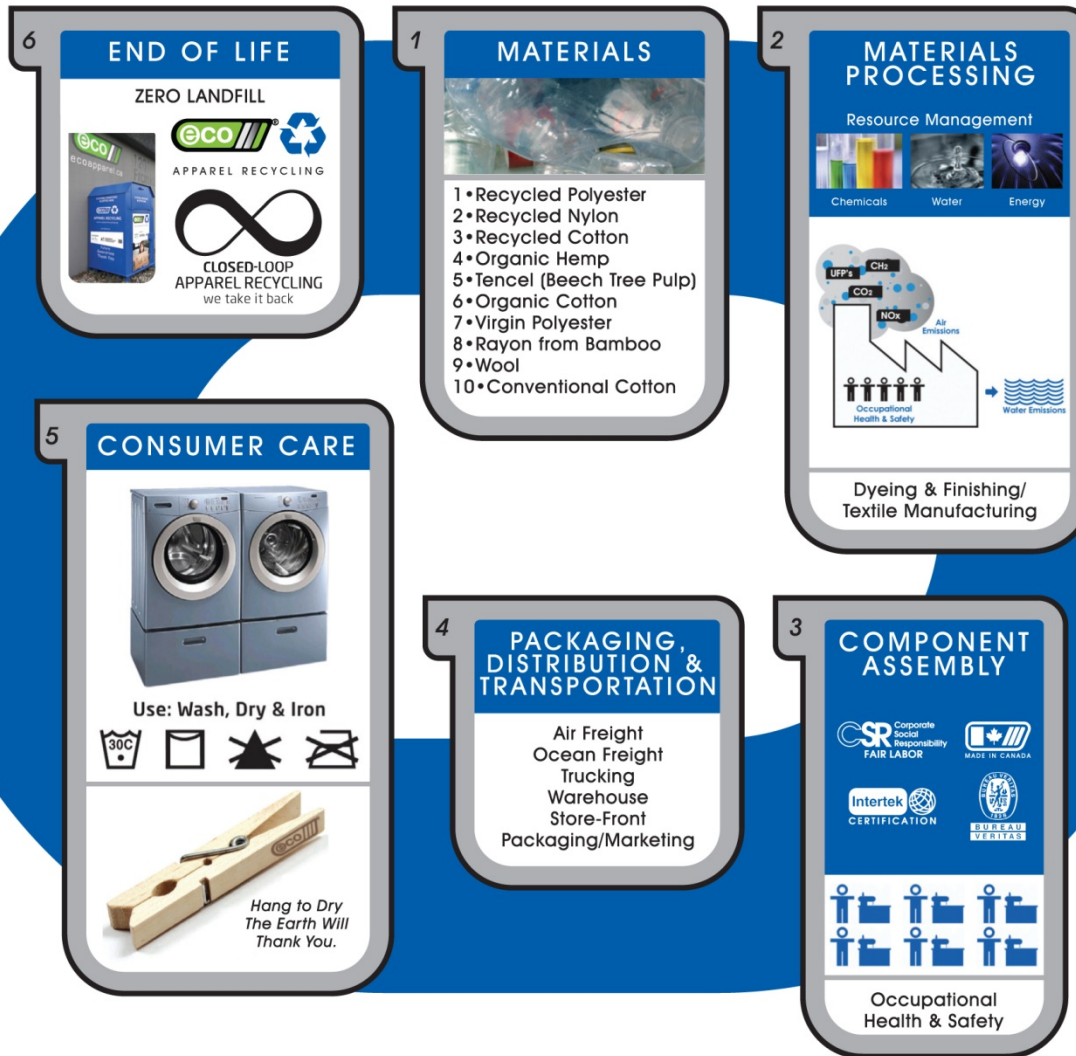
Timelines and Planning

- Educate your clients on the importance of planning ahead to allow for creative and well thought out products.
- We use the ‘risk’ lens when discussing the importance of being able to select good products and good suppliers.

Principles and Policies Unaligned

- Sixty-two percent of respondents said their company CEO has a strong commitment to sustainability; however, only 16 percent said their company has a chief sustainability officer.
- Sixty plus percent of top companies have Corporate Social Responsibility policies but less than a quarter of those have sustainable purchasing policies.
- Our 'buyers' are often junior staff who may not view promotional purchases through a strategic or risk based lens.

LIFE CYCLE STAGES AND AREAS OF IMPACT OF TEXTILE PRODUCTION



Areas of Impact:

- Land Use Intensity
- Water
- Biodiversity
- Chemistry/Toxics
Human Health
- Chemistry/Toxics
Environment
- Energy Use/
GHG's

RECYCLED POLYESTER - HOW IT'S MADE



Step 1:

Plastic PET containers are picked up at community recycling centers, then sorted by type and color.

Step 2:

They are stripped of their labels and caps, washed and crushed, then chopped into flakes.

Step 3:

The flakes undergo a second melting and are made into consistently shaped pellets.

Step 4:

The pellets are melted and extruded to make fiber. The fiber is crimped, cut, drawn and stretched, then baled.

Step 5:

The baled fiber can be processed into fabric for a variety of textile product end uses.

TurboTest*

Don't know where to start? This intuitive online roadmap will help you ascertain what rules, regulations and tests apply to your product.

Progress: 11% Complete

PPAI TurboTest a product safety roadmap



First, we'll gather more information about you and how you'd like to use this service.

TurboTest*

Don't know where to start? This intuitive online roadmap will help you ascertain what rules, regulations and tests apply to your product.



Progress: 32% Complete



PPAI TurboTest a product safety roadmap

REGULATIONS FOR CHILDREN'S PRODUCTS

In its undecorated state, is the item generally considered a children's product?

- ☐ Yes
- ☐ No
- ☐ I don't know

[<< Previous](#)

[Next >>](#)

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Remember

- *Most* pens are general use
- Think before you include a picture of a child interacting with the item on your website or in your advertising
- Look for tracking labels—no one size fits all solution
- Test reports should include pictures
- If it is a children's product, ask for the CPC
- No drawstrings!
- Ask your screenprinter for ink test reports
- Look for the secondary tracking label
- Even if the item is a general use item, there may be regulations beyond CPSIA

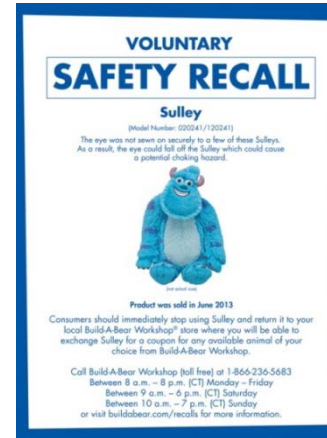
How can these regulations affect my company?



Violations can be costly, damage a company's brand, and establish a "prior offense" that will can result in higher fines and penalties in the future.



Product safety and compliance problems can damage relationships with clients and brand partners.



Safety recalls may result; are very expensive and will damage a company's brand. Claims and suits arise often. May result in greater gov't scrutiny.



A good compliance track-record builds equity with customers, the supply chain, investors and regulators.

What can you do?



- Learn about the various regulations
- Education programs and webinars
- Build compliance into your systems and programs
- Increase your value to your channel partners by ensuring all systems are compliant
- Make yourself and our channel partners hard targets

Best Practices: Key Elements of a Robust Product Safety Program

- Compliance does not mean Safety
- Top leadership commitment
- Transparency
- Document, Document, Document
- Trust but verify

The cost of testing is a tiny fraction of the costs associated with recalls and violations

Leveraging Your “Network”: Insurance Company Insights to Enhance Product Safety

- Insurance is key component in a risk management toolkit
- Product Liability Prevention Program
 - Management coordination and control
 - Design/product development
 - Product warnings and instructions
 - Manufacturing/quality control
 - Sales/marketing statements
 - Vendor management
 - Legal oversight
 - Monitor field service
 - Document control
 - Post-sale management

Now Trending: Advertising's Shared Connections with Safety Regulations

- Social Media is a powerful tool
- Marketing claims must be truthful
 - CPSC – product safety and compliance
 - FTC – marketing claims accuracy / truth in advertising

Regional/Trade: The Trade Overlay-Product Safety and Compliance Implications from TransAtlantic Negotiations

- TTIP: Transatlantic Trade and Investment Partnership agreement
 - Largest economic relationship in the world
 - Very significant trade agreement
 - Addresses trade barriers that arise from different regulatory costs and redundant testing requirements
 - There is a real opportunity for companies to get involved and help to shape discussion.
 - This will also create opportunities for regulators to collaborate once the agreement is established
 - This isn't about harmonizing regulations but there are a number of tools you can use to eliminate some areas of redundancy.

Incorporating Human Factors Principles in Consumer Product Design

"Safety Hierarchy"

- Design
- Guard
- Warn



Where do you find practical guidance?

- ISO Committee on consumer policy (COPOLCO) requested a project be initiated
- In 2009, ISO PC 243 was formed to write ISO 10377

Purpose of ISO 10377

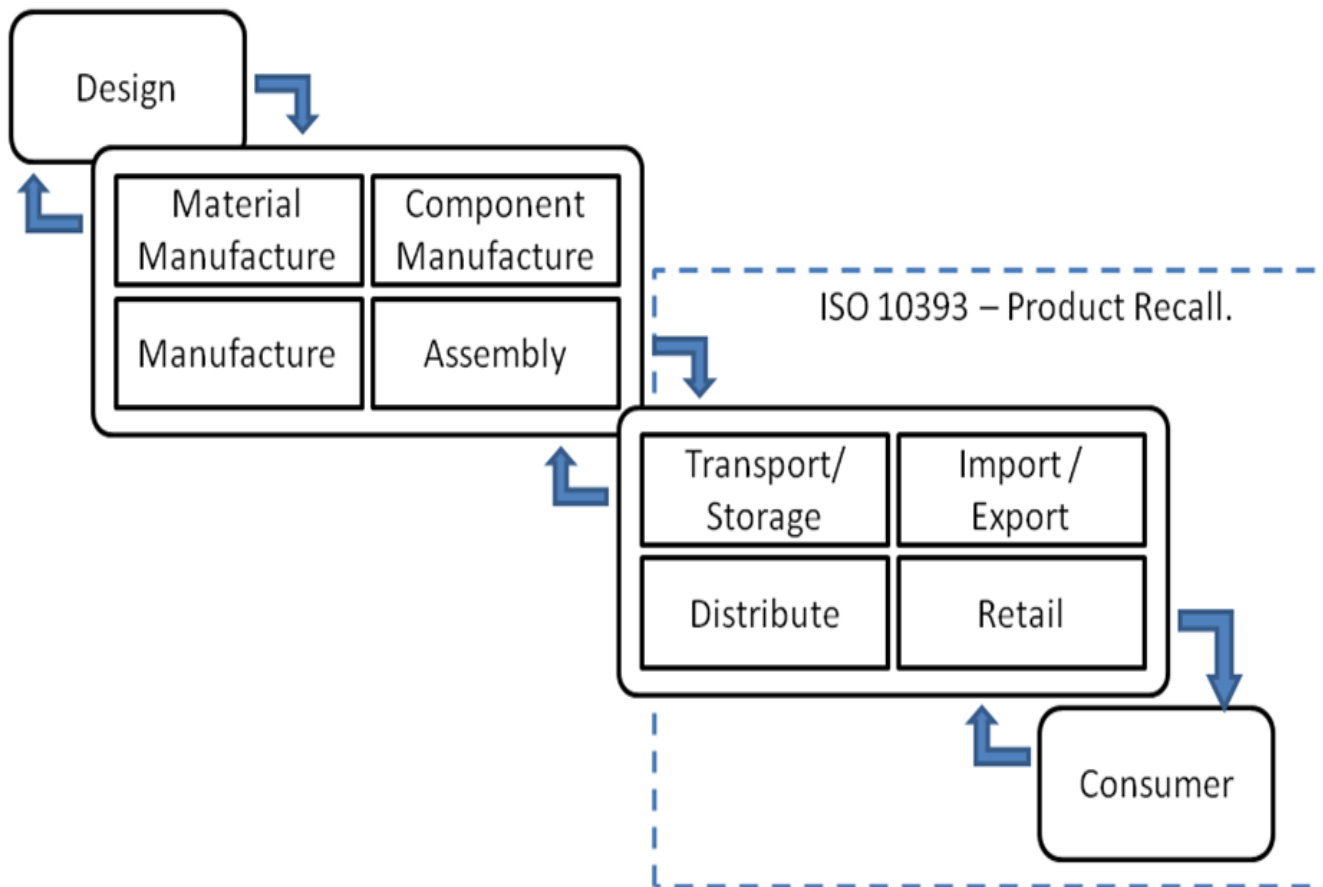
1. Reduce the product safety risk to consumers
2. Reduce the risks to suppliers
3. Provide consumers with the information they need in order to make informed choices with respect to the safe use and disposal of consumer products
4. Assist governments by improving the safety of consumer products

Design

Production

Marketplace

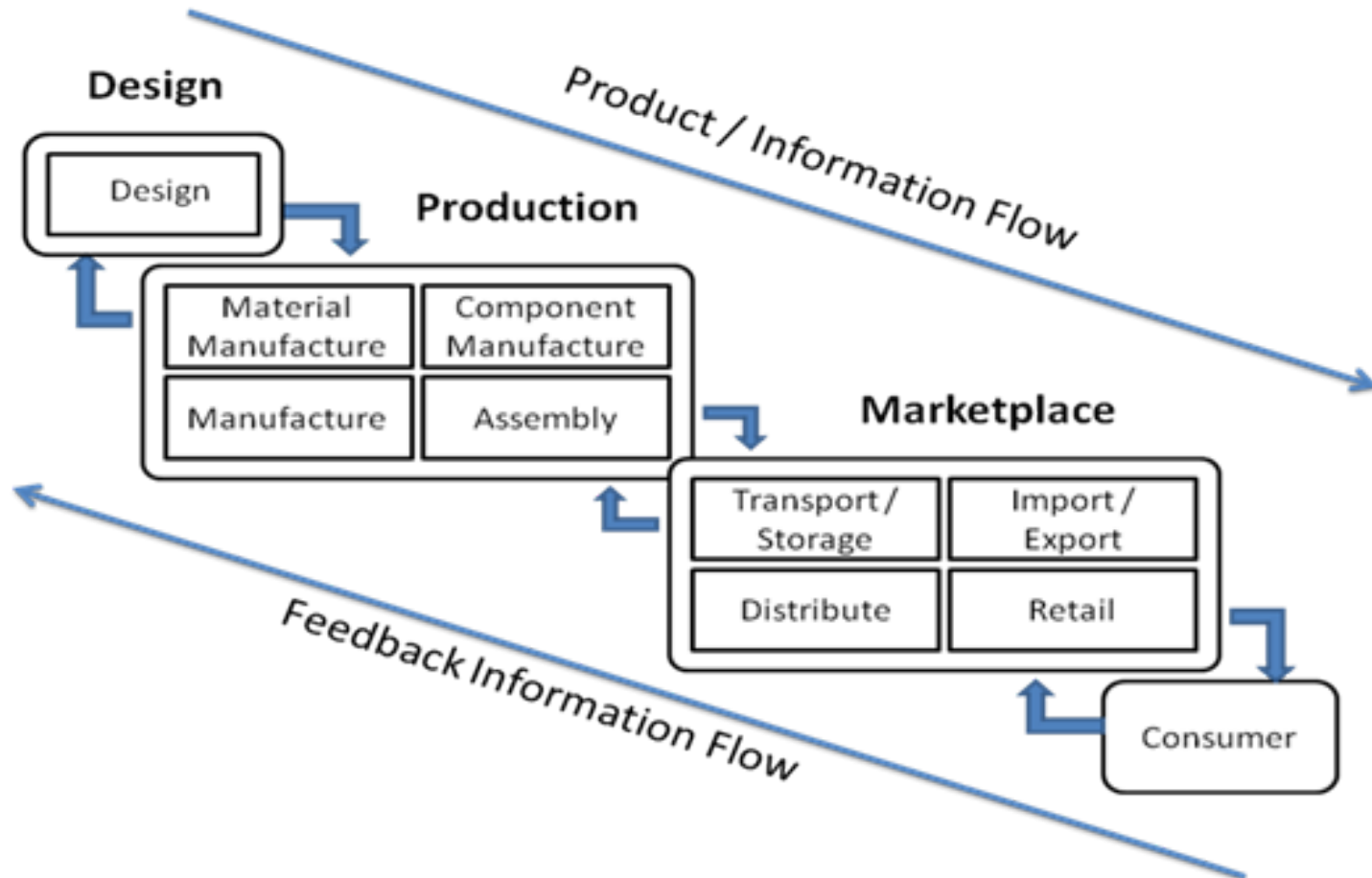
ISO 10377 – Consumer Product Safety Practical Guidance for Suppliers



Basic Principals

1. Promoting a product safety culture within the organization
2. Promoting a product safety culture outside the organization
3. Commitment to providing safe products
4. Continual improvement
5. Precautionary approach
6. Sharing information

The Supply Chain

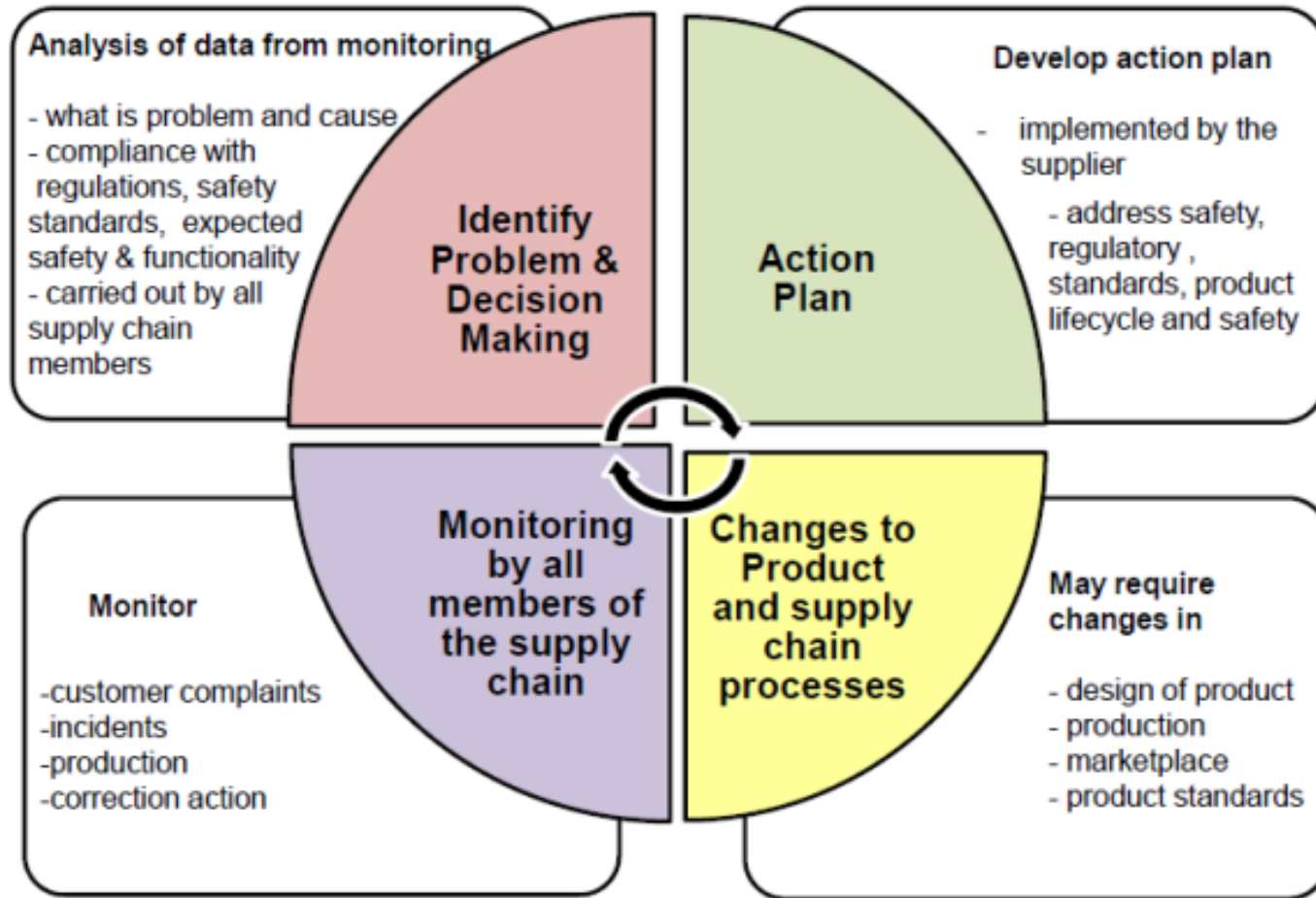


Commitment to providing safe products

1. Competency and training
2. Adequate resource allocation
3. Records management and document control



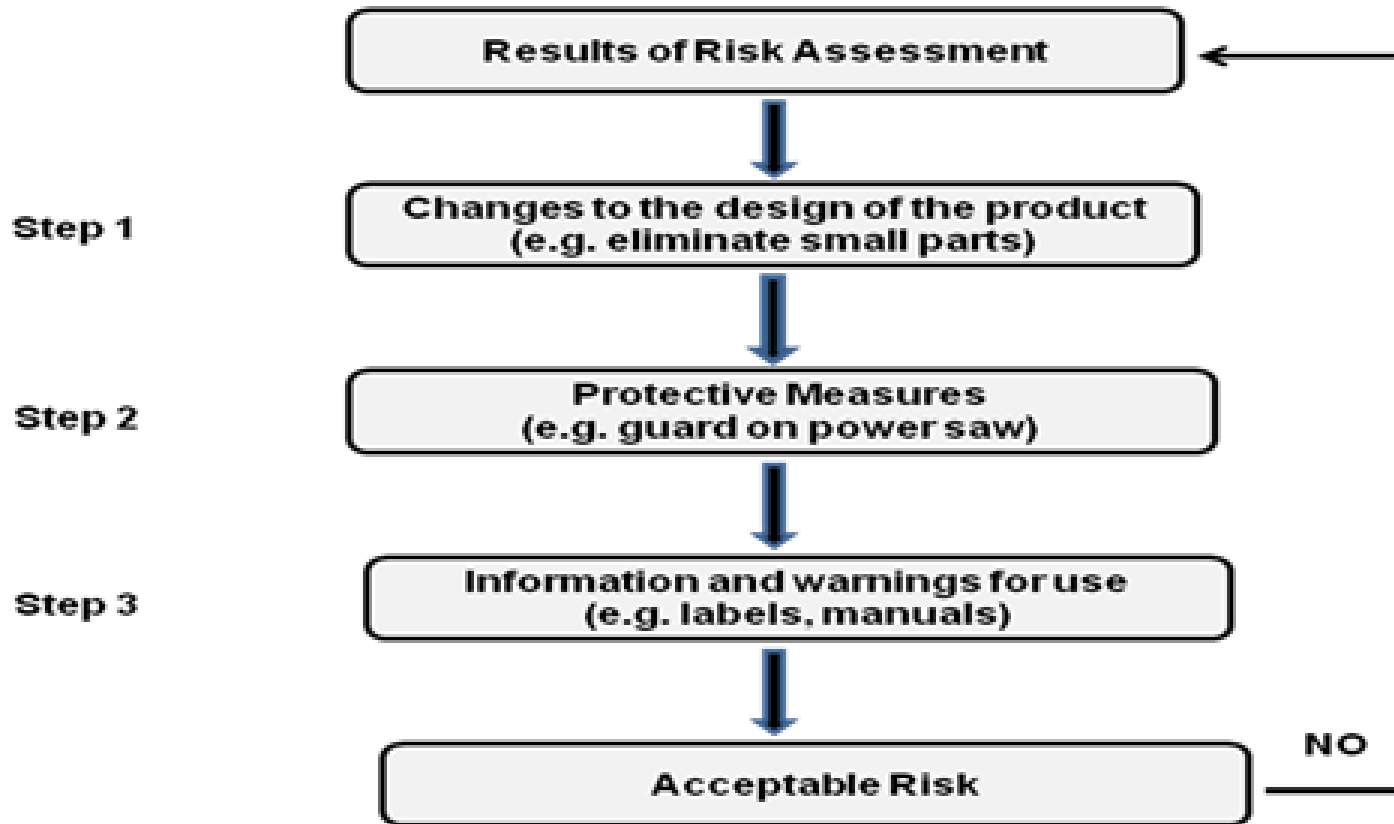
Continual Improvement



Understanding the role of Consumers

1. Will consumers understand the intended use of the products or limitations on use?
2. How will consumers use your product?
3. Will your product be used by vulnerable consumers (children, elderly, disabled)?

Risk Reduction



2014 Legislative Highlights

- DATA Act- Creates government spending transparency; Will be implemented in 2015
- Senate Finance Committee Chairman Max Baucus resigns and Senator Ron Wyden tax the gavel
- MAP 21- Suggested updates made by Department of Transportation
- Tax Refom- Proposals are submitted in House and Senate in July
- Fair Pay Executive Order- Released in August
- Oversight Committee- Indicts Department of Labor on government spending
- Tax Technical Corrections- Chairman Dave Camp releases language for tax corrections
- Midterm election changes political landscape for 2015
- GSP- PPAI joins coalition to renew GSP
- Both houses pass tax extenders
- Both houses pass CR/ Omnibus budget package

Safety In Production



1. Safety Culture
2. Verification of raw materials, components and subassemblies
3. Production Quality Monitoring
4. Finished Product Testing

Safety in the Marketplace

1. Pre-purchase agreement
2. Proactive data collection
3. Ongoing assessment of product conformance
4. Warranty and servicing
5. Product incident investigation (ISO 10393 Product Recall)



Differentiation Through Corporate Responsibility

- Don't just take the orders
- Go beyond just selling products
- Use your product responsibility knowledge to differentiate yourself from your competition
- Position yourself as an indispensable resource
- Be a partner to your customer
- Be a brand steward

Engage in the Conversation

- Share with your customer
 - The basic laws and regulations
 - Your obligation and responsibility to the laws and regulations
 - Your obligation and responsibility to protecting their brand and image
 - That by working together the two of you can ensure they have the right product for the right audience
 - In the end it's about protecting and promoting their brand with a memorable, engaging and long-lasting program

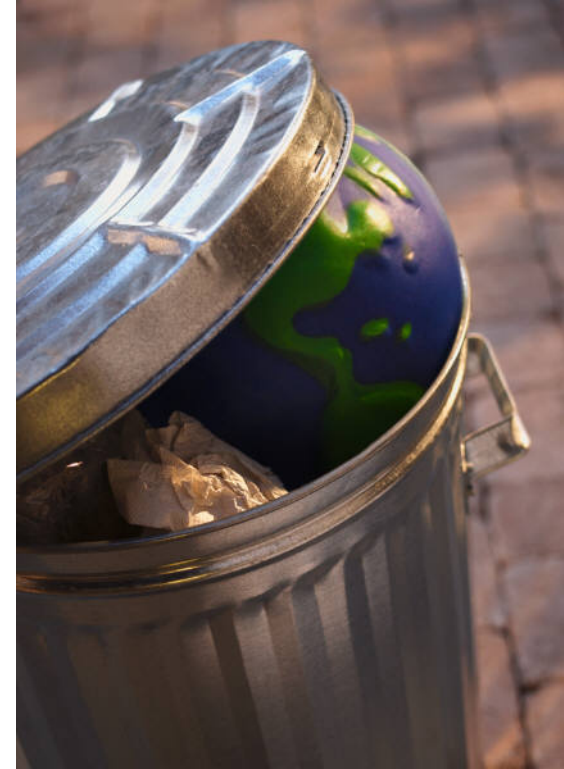
Engage in the Conversation

- Social Responsibility
- Code of Conduct
- Company/Organization Message and Mission



Engage in the Conversation

- Environmentally responsible manufacturing practices
- Recycled vs. Recyclable
- Reusability (avoid the trash)
 - Will product serve customer's purpose or end up in a landfill?



Ask the Questions No One Else Will

- Who is the intended audience?
 - *Will this item be distributed to children?*
- How will the products be distributed?
- What kind of logo do you intend to use?
- What's the intended outcome?



Ask the Questions No One Else Will

- Do you typically keep items in stock for future use or do you distribute all items?
- Do the customer's preferred products have child like appeal or playful elements? Or do those products have “diminishing appeal” to the 12 and under crowd?



Distributors - Tell Your Suppliers

- The intended audience
- If the item will be given to children
- The distribution method
 - Certain events or delivery could encourage unintended distribution to children
- The product you want



Distributors - Ask Your Suppliers

1. Is the item considered a children's product?
2. What regulations apply?
3. Does the product comply with all applicable regulatory requirements?
4. How has compliance been determined?
5. Request copy of all related test reports

Distributors - Ask Your Suppliers

6. Was all product made at the same factory?
7. Was all product made from the same lot of materials?
8. If a children's product, what does the tracking label information mean?
9. Will the modifications you plan to make to the product affect the product's compliance?

Best Practices

- Strong Corporate Responsibility systems and strategies
 - Provide Direction
 - Simplify the product responsibility process
 - Need to be part of your sales culture
 - May provide some protection against challenges

Purchase Order Best Practices

- Create fields on all purchase orders that require answers to the following questions:
 - Is this a children's product?
 - Will children be recipients of this product?
- If the answer to both of these questions is yes, it is important to note clearly on the purchase orders:
 - This product is intended for distribution to children. It must comply with all applicable federal and state regulations.

Differentiation Best Practices

- Add corporate responsibility to the mix
 - Comfort comes with repetition
- Back up your talk
 - Establish guiding principles
 - Properly vet suppliers
 - Make sure preferred suppliers share your values
 - Communicate your principles and best practices to your clients



Accessible

- You do not need to be an expert
- You do need to be familiar and aware
- PPAI has the tools to guide you through the process



Product Safety Aware

- Creates confidence in promotional products as an advertising medium at every level
- Required program elements
 - CAS Required Product Safety Basics: 60-90 minutes
 - Prop 65 and State Regulations: 60 minutes
 - Undue Influence Training: 60 minutes
- Elective program elements
 - Any additional session from an approved list

Product Safety Aware

- Live webinars
- On-Demand Webinars
- Expo East
- Regional Associations
- Product Safety Summit
- Expo 2015



Adopt and Promote the PPAI Code of Conduct

W E A B I D E B Y T H E



PPAI CODE
OF CONDUCT

How PPAI Can Help

- Product Safety powered by PPAI
 - Webinars
 - Best Practices
 - Turbo Test
 - Tracking Label system
 - Product Protocols
 - Code of Conduct

